2014-1764, 2014-1791

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

KONINKLIJKE PHILIPS N.V. and
PHILIPS ELECTRONICS NORTH AMERICA CORPORATION,

Plaintiffs-Appellants,

v.

ZOLL MEDICAL CORPORATION,

Defendant-Cross Appellant.

Appeals from the United States District Court for the District of Massachusetts in Case No. 1:10-cv-11041-NMG Judge Nathaniel M. Gorton

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BRIEF OF PLAINTIFFS-APPELLANTS KONINKLIJKE PHILIPS N.V. and PHILIPS ELECTRONICS NORTH AMERICA CORPORATION

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November 26, 2014

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CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants Koninklijke Philips N.V. and Philips Electronics North America Corporation certify the following:

1. The full name of every party or amicus represented by me is:

   Koninklijke Philips N.V. (formerly Koninklijke Philips Electronics N.V.); Philips Electronics North America Corporation

2. The name of the real party in interest represented by me is:

   Koninklijke Philips N.V. (formerly Koninklijke Philips Electronics N.V.); Philips Electronics North America Corporation

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

   Philips Electronics North America Corporation is a wholly owned subsidiary of Philips Holding USA, Inc., which, directly and indirectly, is a wholly owned subsidiary of Koninklijke Philips N.V.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

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STATEMENT OF RELATED CASES

There has been no other appeal from the present civil action in this or any other appellate court.

Appeal Nos. 14-1588, 14-1589, 14-1590, 14-1591, 14-1592, 14-1593, 14-1594, and 14-1595 involved the same Philips patents at issue in this appeal or related patents. These appeals were taken from decisions of the Patent Trial and Appeal Board dismissing petitions for inter partes review of the Philips patents. These appeals were consolidated and dismissed on August 25, 2014.

STATEMENT OF JURISDICTION

(a) The statutory basis for jurisdiction of the trial court was 28 U.S.C. § 1338(a).

(b) The statutory basis for jurisdiction of this Court to hear this appeal is 28 U.S.C. § 1292(c)(2), the district court having issued a final judgment except for an accounting on June 20, 2014, which became appealable on August 13, 2014, when the district court denied Philips's motion for judgment as a matter law under Rule 50(b).

(c) This appeal was timely filed on August 14, 2014, in accordance with 28 U.S.C. § 2107 and Fed. R. App. P. 4(a).

I. STATEMENT OF THE ISSUES

1. Did the district court err in denying Philips's motion for judgment as a matter of law that Zoll is a contributory infringer of Philips's waveform patents, where (a) the jury found that Zoll's defibrillators directly infringed, and customers undeniably use Zoll's defibrillators to defibrillate; (b) Zoll intentionally altered its website to disguise its infringement after Philips sent letters to Zoll explicitly identifying infringement; and (c) the defibrillation feature in Zoll's defibrillators is separate and distinct from other functionalities and has no noninfringing uses?

2. Did the district court err in denying Philips's motion for judgment as a matter of law that Zoll is a contributory infringer of Philips's self-test patents, where (a) Zoll admitted that its defibrillators automatically infringed, and customers undeniably use Zoll's defibrillators to run infringing self-tests; (b) Philips sent letters to Zoll explicitly identifying infringement nearly two years before filing suit; and (c) the self-test features in Zoll's defibrillators are separate and distinct from other functionalities and have no noninfringing uses?

3. Did the district court err by failing to find the claims of the '526 patent indefinite where their scope is so uncertain that an accused product can be both infringing and noninfringing depending on a range of test conditions not disclosed in the patent?

4. Did the district court err when it instructed the jury that only claims that are insolubly ambiguous are indefinite?

5. Did the district court err by excluding prior art merely due to the form of the documents where evidence showed that those documents and products qualified as prior art?

II. STATEMENT OF THE CASE

A. Preliminary Statement

This case is about external defibrillators. Five inventors in the early 1990s, frustrated with the direction of the company they worked for, set out to improve the speed, safety, and accessibility of an inherently risky procedure: shocking the human heart with electrical energy. They created a start-up company called Heartstream. They also applied for and received two groups of patents that would revolutionize the external defibrillator industry and ultimately save lives.

The first group of patents—U.S. Patent Nos. 5,607,454 and 5,749,905 (the "waveform" patents)—is directed to defibrillators that deliver an optimized defibrillation shock or waveform by automatically compensating for patient-to-patient differences in resistance to the flow of electricity. The claimed impedance-compensating technology saves crucial seconds and minimizes adverse effects by enabling external defibrillators to quickly and automatically adjust the energy waveform depending on the physiology of the particular patient needing treatment.

The second group of patents—U.S. Patent Nos. 5,879,374 and 5,800,460 (the "self-test" patents)—is directed to an external defibrillator that tests itself automatically without user involvement. Before these patents, defibrillator testing required user intervention. Self-tests that run automatically and periodically without user involvement ensure that the defibrillators remain functional and ready for use in an emergency, even when left unused for long periods of time.

Until the mid-1990s, external defibrillators were primarily designed for hospitals, where trained professionals used them many times a week. Trained hospital technicians would test them to assure their operability. But nonhospital defibrillators (commonly referred to as automatic external defibrillators or "AEDs") received far less attention. The inventors believed that their impedance-compensating waveform and periodic self-test technologies made defibrillators reliable enough to be used in public places by untrained people.

In 1996, Heartstream introduced its first AED intended for public places—the ForeRunner, which *Popular Science* recognized as one of the 100 greatest achievements in science and technology for the year. Appreciating the value and importance of the waveform and self-test technologies, Philips acquired this technology and continued to successfully market and sell external defibrillators using it, including the HeartStart Home defibrillator. *Forbes* named the HeartStart Home one of "Ten Gadgets that Will Improve Your Life" and one of the ten most

"disruptive" products from 1997-2007, along with Netflix, Google, the iPod, Skype, and YouTube. AEDs are now ubiquitous in public places, in large part because of the waveform and self-test technologies.

Enter Zoll. Like Philips, Zoll manufactures, tests, and sells external defibrillators. But Zoll was late to the AED market. Looking to grow and lagging in innovation, Zoll incorporated the impedance-compensating waveform and periodic self-tests into its defibrillators. In fact, Zoll's CEO, Richard Packer, testified that Zoll included the automatic self-tests in its defibrillators so it could enter the public-access defibrillator market.

Philips sued Zoll for infringement in 2010, and the jury found that Zoll's defibrillators directly infringed the waveform and self-test patents. Despite this finding, the jury did not find that Zoll contributed to their customers' infringement. But Philips had presented unrebutted evidence that Zoll knew of the waveform and self-test patents and of its infringement. Indeed, in response to notice letters from Phillips detailing Zoll's infringement, Zoll changed the description of its defibrillator on its website but not the defibrillator itself. Likewise, the unrebutted evidence showed that Zoll's defibrillators have no substantial noninfringing uses. There is no use for Zoll's defibrillator circuitry and waveform other than delivering a shock through the claimed method. Similarly, there is no use for Zoll's self-tests other than carrying out the self-tests claimed in Philips's patents. Given this

unrebutted evidence, there is no legally sufficient basis for a reasonable jury to find no contributory infringement.

In contrast to Philips's patents covering fundamental technology that enabled the defibrillator market we see today, Zoll asserted two patents on minor features against Philips, including U.S. Patent No. 5,330,526 directed to the gel used on a defibrillation electrode that gets attached to a patient's body. The '526 claims require that the electrode gel have a resistance greater than 1 Ω when measured by a testing procedure. But the '526 patent does not disclose important test conditions that impact the measured resistance, such as temperature, number of shocks, and age of the electrode.

The undisputed evidence showed that an electrode could be measured to be infringing or noninfringing depending on these conditions. This is the epitome of an indefinite claim—Philips could not have determined the scope of the claim with any certainty. The jury did not find the claims invalid, but it was instructed that "only" claims that are insolubly ambiguous are indefinite. Here, the undisputed evidence shows that the scope of the '526 claims is not reasonably certain and thus the claims are invalid as indefinite.

B. Nature of the Case, Course of Proceedings, and Disposition Below

Philips sued Zoll in the U.S. District Court for the District of Massachusetts, alleging that Zoll infringed several patents, including Philips's waveform and self-

test patents. A132; A191. Zoll also sued Philips in the same court, alleging that Philips infringed patents, including the ’526 patent. A5550-59. Zoll’s claims were consolidated with Philips’s suit. A194-95.

After a trial in December 2013, the jury found that Zoll’s AED Plus, AED Pro, R Series, E Series, M Series, and X Series defibrillators directly infringed claim 51 of the ’454 waveform patent and claims 4 and 8 of the ’905 waveform patent.[1] A108-09. The jury also found that Zoll’s AED Plus and AED Pro defibrillators directly infringed claims 42, 43, 67, and 68 of the ’374 self-test patent and claim 7 of the ’460 self-test patent; the R Series defibrillator directly infringed claims 42, 43, 67, and 68 of the ’374 self-test patent; and the X Series defibrillator directly infringed claim 43 of the ’374 self-test patent. A105-06. The jury further found that Zoll did not prove Philips’s patents to be invalid. A105-13. But the jury did not find for Philips on Zoll’s contributory infringement of the waveform and self-test patents. A105-10.

For Zoll’s patents, the jury found that one of Philips’s defibrillators infringed Zoll’s U.S. Patent No. 5,391,187, and that some of Philips’s electrodes infringed Zoll’s ’526 patent. A114-15. The jury further found that Philips did not prove Zoll’s patents to be invalid. A116. The district court denied both parties’

[1] Philips also asserted U.S. Patent Nos. 5,836,978 and 6,047,212 against Zoll, but those patents are not at issue in Philips’s appeal.

Rule 50(b) motions[2] for judgment as a matter of law (A7; A9), and this appeal followed.

III. STATEMENT OF FACTS

A. Philips's Waveform and Self-Test Patents

1. Development of the Revolutionary Technology in the Waveform and Self-Test Patents

When the heart contracts without coordination, normal blood flow to the body is dangerously interrupted. A370 at 1:21-25. This chaotic state, known as ventricular fibrillation, is treated by defibrillating or shocking a patient's heart with electrical energy. *Id.* at 1:22-27. Timing is critical, and minutes can be the difference between life and death. *Id.* at 1:28-35. The sooner a heart can be defibrillated, the higher the chances of survival. *Id.*; A2031:1-11. The rate of survival for a victim of cardiac arrest decreases 10% for every minute that passes without defibrillation. A1396:25-A1397:15; A1407:20-A1409:7; A2031:1-11.

Five inventors in the early 1990s sought to improve the speed, safety, and accessibility of defibrillators. These inventors thought that lives could be saved if they could get defibrillators into public places where they would be accessible. A2019:15-21. The inventors created a company called Heartstream, and

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[2] Philips filed Rule 50(a) motions for judgment as a matter of law on December 16, 2013 (A301), which the district court denied on June 20, 2014 (A10-12).

developed technology to make defibrillators safer and more accessible. Specifically, these inventors developed a way to optimize a defibrillation shock or waveform by automatically compensating for patient-to-patient differences in resistance to the flow of electricity, that is, differences in patient impedance. No two patients are identical so the optimal shock for each patient is not identical. These inventions led to the waveform patents—the ’454 and ’905 patents.

These inventors also recognized that the frequent testing required for defibrillators limited where they could be used. It was unrealistic to expect the average person to be able to adequately test a defibrillator and ensure that it would operate reliably when called on to save a life. The inventors developed technology enabling a defibrillator to test itself automatically without the user having to turn it on or be involved. These self-tests occur before the defibrillator is even powered on to ensure that it remains functional and ready for use in an emergency. These inventions led to the self-test patents—the ’374 and ’460 patents.

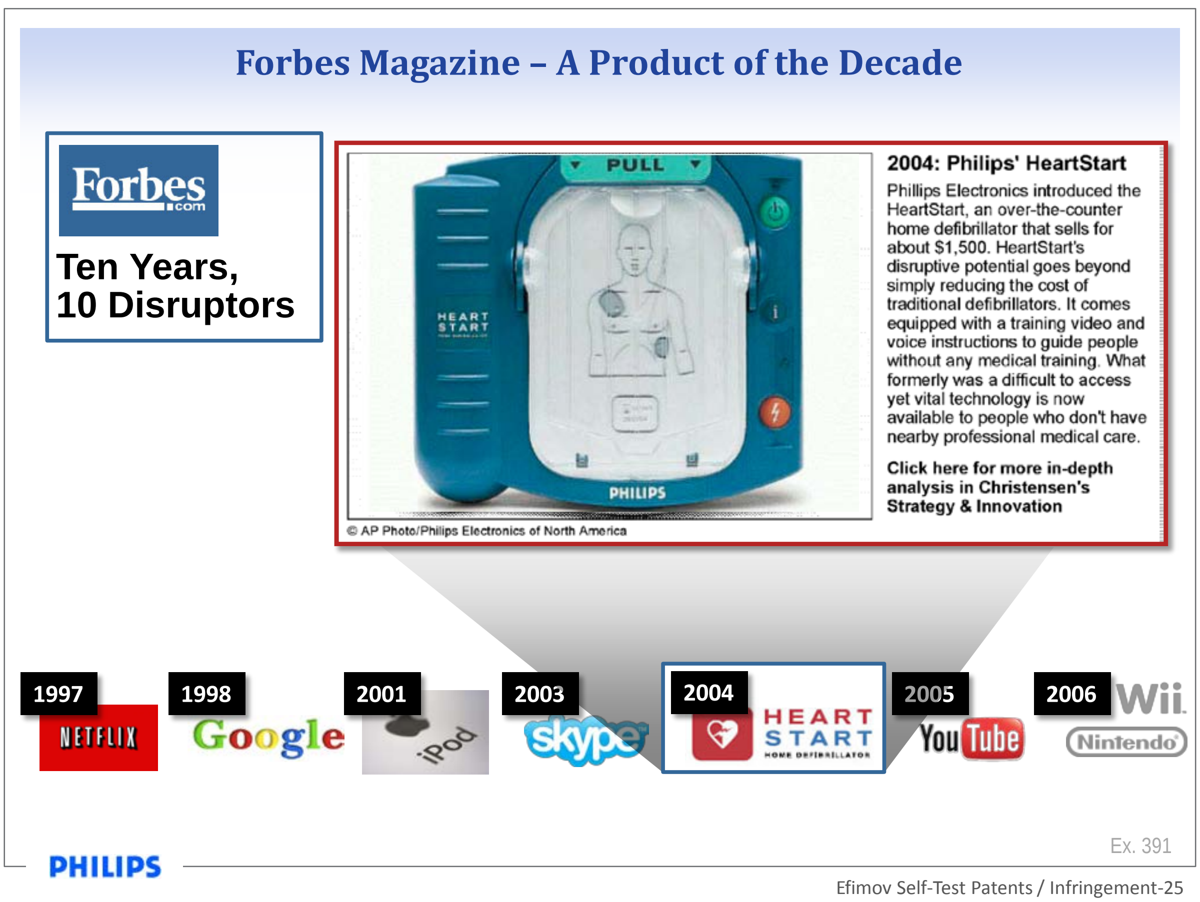
Before the waveform and self-test patents, external defibrillators were primarily used in hospitals by trained professionals. Nonhospital defibrillators or AEDs were less prevalent. The Heartstream inventors believed that their inventions made defibrillators reliable enough to be used in public places by untrained people, and Heartstream introduced its first AED intended for public places—the ForeRunner—in 1996. It incorporated Heartstream’s

impedance-compensating waveform technology and ran periodic self-tests before power on. A14460; A14474-75; A14503.

At first, Heartstream had difficulty convincing companies to buy the ForeRunner. A2023:14-A2024:5. There were concerns about putting a device that could kill someone if not used properly in the hands of the public. Heartstream's big break came when American Airlines decided to put a ForeRunner on every plane in its fleet. A2024:6-A2030:23. Heartstream never looked back. In 1997, *Popular Science* recognized the Heartstream ForeRunner as one of the 100 greatest achievements in science and technology for the year. A12702-05; A2026:3-14.

These achievements did not go unnoticed. The Heartstream business—including the self-test and waveform patents—was acquired, first by Hewlett-Packard in 1998, and then by Philips in 2001. A2018:16-A2022:17. Deborah DiSanzo, Philips's CEO and former Marketing Manager of Hewlett-Packard's Cardiology Products Division, testified that Hewlett-Packard bought Heartstream because these "technologies for low-energy biphasic and self-test were very important to build this new [AED] market." A2022:12-14. Building on Heartstream's success, Philips continues to successfully market and sell defibrillators featuring the waveform and self-test technologies. A1321:2-A1324:23; A1326:24-A1327:20; A1347:24-A1353:21; A1354:20-A1355:22; A1486:19-24; A12696; A12698; A17187-96; A17230; A17250.

In 2004, Philips's HeartStart Home defibrillator became the first defibrillator approved for over-the-counter sale without a prescription, a feat that, even at the time of trial, no other company had matched. A2030:14-A2033:3. Today, the HeartStart Home is available for purchase at places like CVS and Amazon. A1318:23-A1319:7; A2032:17-A2033:3. *Forbes* named the HeartStart Home one of "Ten Gadgets that Will Improve Your Life." A12714-24. *Forbes* also named Philips's HeartStart Home one of the ten most "disruptive" products from 1997-2007, along with Netflix, Google, the iPod, Skype, and YouTube. A12725-34.



Once met with resistance, AEDs can now be found everywhere—primarily because of the waveform and periodic self-test technologies. A1354:20-A1355:22; A1406:22-A1409:7; A2021:8-A2022:17; A2024:9-23; A2030:14-23. In the defibrillator field, early treatment can be the difference between life and death. And when seconds are vital, the importance of having defibrillators readily accessible at gyms, hotels, airports, etc., cannot be overstated.

2. The Waveform Patents

Philips's '454 and '905 patents relate generally to defibrillators that automatically compensate for patient-to-patient differences in the delivery of electrical energy (a waveform) to the patient. The resistance of a patient's body against the flow of electricity, referred to as the patient's impedance, varies from person to person depending on factors such as weight, size, and body type. A370 at 2:31-43. A 90-pound woman will not conduct electricity the same way as a 400-pound man. A1321:13-24. Thus, the energy level required for successful defibrillation varies from person to person.

Prior-art external defibrillators did not adequately address the patient-variability problem. A370 at 2:55-56; A448 at 2:20-21. Instead, a typical defibrillator had multiple user-selectable energy settings. A370 at 2:56-65; A448 at 2:23-30. An operator would first attempt to defibrillate the patient by setting an energy level appropriate for a patient of average impedance. A370 at 2:56-65;

A448 at 2:23-30. If the first shock did not work, the operator would raise the energy level and try again. A370 at 2:56-65; A448 at 2:23-30. This process, however, added patient risk and reduced efficiency. A370 at 2:56-65; A448 at 2:23-30. When seconds mean the difference between life and death, repeated attempts to find the correct defibrillation waveform can cost lives. In addition, most prior-art defibrillators delivered monophasic pulses, which required higher voltages and higher total delivered energies than biphasic waveforms (a waveform with two phases). A370 at 2:5-10; A448 at 1:53-56.

To solve these problems, the waveform patents disclose devices and methods for automatically measuring a patient-dependent parameter (such as current or voltage, which is then used to calculate impedance) during discharge, and then automatically adjusting the waveform depending on the measured parameter. A363 at Abstract. The claimed impedance-compensating technology saves lives by automatically delivering a safer and more effective shock on the first try. A1400:17-A1406:15.

Claim 51 of the ’454 patent and claims 4 and 8 of the ’905 patent are at issue in Philips’s appeal:

> 51. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:
>
> charging the energy source to an initial level;

> discharging the energy source across the electrodes to deliver electrical energy to the patient in a waveform, the patient and an additional impedance forming an electrical circuit with the energy source;
>
> monitoring an electrical parameter during the discharging step;
>
> removing the additional impedance from the electrical circuit if the electrical parameter is within a defined range prior to the end of the discharging step.

A376.

> 4. A method for delivering electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:
>
> discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;
>
> monitoring a patient-dependent electrical parameter during the discharging step;
>
> shaping the waveform so that an initial parameter of a waveform phase depends on a value of the electrical parameter.
>
> 8. The method of claim 4 wherein the initial parameter is current.

A391.

3. The Self-Test Patents

Philips's '374 and '460 patents are directed to external defibrillators that perform self-tests periodically without user involvement.[3] A421-37; A392-406. The types of self-tests disclosed are comprehensive and include tests of defibrillator circuitry, the battery, and the CPU. A429-30 at 2:57-3:10.

The self-test patents recognize that self-tests run automatically before turning on the defibrillator eliminate the burden and cost associated with maintaining the defibrillators in a constantly operable state. A429 at 1:36-46, 2:3-7. Without that burden, hospital staff can devote more time to other needs besides defibrillator testing. And, because defibrillators would no longer require around-the-clock maintenance from trained personnel, their widespread dissemination became possible. A429 at 1:36-46; A1406:22-A1409:7. Indeed, the technology claimed in the self-test patents opened a new market for AEDs—a "public access" market that included schools, churches, airports, and even homes. A12715 (*Forbes* article emphasizing daily self-test to ensure the device "won't malfunction in a medical emergency").

Even Zoll's CEO, Richard Packer, testified that "the market has moved in th[e] direction" of automatic self-testing even for professional hospital

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[3] The district court construed "prior to any attempted use" in claims 42 and 67 of the '374 patent to mean "prior to an operator turning on the defibrillator." A85.

defibrillators because of "the labor pressures that are on hospitals for nursing staff." A1943:22-A1944:11. He explained that Zoll first added automatic self-testing to its AED Plus in 2002 because, "in that market where you are going to have a defibrillator that is stationed someplace and there isn't a user that's expected to interact with it, . . . it doesn't make sense to expect a manual test to be performed on a regular basis." A1943:11-21.

Claims 42, 67, and 68 of the '374 patent and claim 7 of the '460 patent are at issue in Philips's appeal:

> 42. A method for automatically determining and indicating an operational status of an external defibrillator, the method comprising the following steps:
>
> generating a test signal within the external defibrillator automatically and periodically;
>
> performing a self-test in response to the test signal; and
>
> indicating the operational status of the defibrillator based on a result of the self-test;
>
> the generating, performing and indicating steps being performed prior to any attempted use of the defibrillator.
>
> 67. A method for testing and indicating an operational status of an external defibrillator comprising the following steps:
>
> generating a test signal within the external defibrillator automatically and periodically;
>
> performing a plurality of self-tests in response to the test signal to determine the operational status of a plurality of components of the defibrillator, the tests being performed without human intervention prior to any attempted use of the defibrillator; and

> indicating the operational status of the defibrillator in response to at least one of the self-tests.
>
> 68. The method of claim 67 wherein the generating step comprises generating a test signal within the defibrillator automatically on a predetermined schedule.

A436-37.

> 1. A method of performing a self-test in an external defibrillator, the method comprising the following steps:
>
> generating a test signal automatically;
>
> turning on a power system within the external defibrillator in response to the test signal; and
>
> performing a plurality of automatic self-tests within the external defibrillator for determining the status of the defibrillator.
>
> 5. The method of claim 1 wherein the performing step comprises performing said plurality of automatic self-tests within the external defibrillator on a schedule.
>
> 6. The method of claim 5 wherein the performing step comprises performing a first automatic self-test on a first periodic schedule.
>
> 7. The method of claim 6 wherein the performing step comprises performing a second automatic self-test on a second periodic schedule.

A406.

4. Trial on Direct and Contributory Infringement of the Waveform and Self-Test Patents

After Zoll refused to license the waveform and self-test patents, Philips filed suit in 2010. A191; A1978:19-A1979:15. The liability phase of the case was tried

in December 2012, where Philips put on evidence of direct and contributory infringement. The jury found that Zoll's defibrillators directly infringed Philips's waveform and self-test patents but did not find contributory infringement. A105-13.

a. Evidence of Knowledge

At trial, it was established that Zoll knew about the waveform and self-test patents for over a decade. Zoll's CEO, Mr. Packer, testified that he was aware that Philips was litigating with other companies on the waveform and self-test patents as far back as 2003. A1983:1-20. Mr. Packer further testified that "[t]his is a small industry. There are three main players. We all know what each of us are doing. We track each other very, very closely." A1965:22-A1966:22. And even before 2003, Zoll had knowledge of the waveform patents: the '454 patent is cited in Zoll patents issuing as early as 1998. A8489; A14774; A18039; A18064; A18084; A1984:5-A1985:23; A1751:19-A1752:14.

Zoll's knowledge was reinforced in 2008, when Philips sent notice letters describing Zoll's infringement of the waveform and self-test patents. A1958:24-A1959:11; A1978:21-A1979:10; A1980:18-A1981:18; A12706-13. Philips's letters were detailed and identified specific patent claims and Zoll documents showing infringement. A12706-13; A1979:1-A1981:3. From 2008 to 2010,

Philips continued to tell Zoll that its defibrillators infringed the waveform and self-test patents. A1979:1-A1980:4.

Zoll's actions in response to Philips's letters speak louder than words. In a 2009 letter, Philips pointed to Zoll's website as proof that its defibrillators infringe the waveform patents. A12706; A1980:18-A1981:3. At the time, Zoll's website explicitly acknowledged that its products measured impedance "[d]uring the first 250 [microseconds] of a shock delivery," thereby satisfying the "during the discharging step" of the waveform patent claims. A8432-33 (emphasis added); A1981:17-A1982:25; A376 at 14:47-60; A391 at 18:17-39. In response, Zoll changed the website's description of its defibrillators, the new description reading, "[a]n impedance test pulse of 250 [microseconds] is applied *prior to* shock delivery." A8434-37 (emphasis added); A1981:17-A1982:25. Yet Zoll did nothing to alter the accused devices themselves. A1981:4-9; A1981:17-A1982:25; A2477:24-A2479:22. Only after fact discovery closed and the experts submitted their reports did Zoll change the way it measured patient impedance and only for one product. A2453:14-A2455:1.

b. Evidence of Infringement

The waveform patents are directed to monitoring an electrical parameter and using that monitored parameter to adjust an aspect or parameter of the waveform. The evidence at trial showed that this methodology is at the heart of Zoll's

waveform, which measures current and then selects a discharge schedule based on that measured current. A14582-85. Philips's expert, Dr. Patrick Wolf, explained how Zoll's defibrillators meet the claims.

For example, for claims 4 and 8 of the '905 patent, Dr. Wolf explained that Zoll's defibrillators discharge their energy sources across electrodes to deliver electrical energy to the patient in a multiphasic waveform (A1633:13-A1634:10; A1637:9-1638:9), monitor a patient-dependent electrical parameter (current) during the discharge (A1634:12-23), and shape the waveform based on that monitored parameter (A1635:1-A1637:6.) *See also* A1630:23-A1633:12; A1638:10-A1658:25. Likewise, Dr. Wolf explained that Zoll's defibrillators execute every step of claim 51 of the '454 patent. A1659:2-A1673:20.

Even testimony of Zoll's Vice President of Design Excellence, Donald Boucher, showed that Zoll's defibrillators are used on patients and practice each step of the asserted claims each time a shock is delivered. A14582-85; A2456:10-A2459:15. Mr. Boucher further testified that Zoll tests all of its defibrillators by delivering shocks to make sure that the energy delivered to patients is as specified (A2481:23-A2482:18), and that Zoll performed clinical testing on human patients for products that are already on the market (A2484:12-21; *see also* A1953:3-9; A2685:12-22; A14568). Mr. Boucher also testified that Zoll's customers used its

defibrillators as intended. A1899:22-A1900:5. And each time those customers use Zoll's defibrillators to defibrillate, they use Zoll's waveform to deliver the shock.

As for the '374 and '460 self-test patents, Zoll did not contest infringement at trial. Zoll's expert, Dr. Henry Halperin, admitted that Zoll's defibrillators infringed the self-test patents. A2909:18-A2910:9.

As with Zoll's waveform technology, Mr. Boucher testified that Zoll tests its defibrillators' self-test features. A2482:19-A2483:16. Likewise, Philip's expert, Dr. Igor Efimov, testified that Zoll conducted validation and verification tests to make sure the self-test features and functionalities of the AED Plus, AED Pro, and R Series defibrillators were working properly. A1897:18-A1898:16; *see also* A1898:17-A1899:2; A13774-75. The evidence also showed that Zoll configures its defibrillators to automatically run self-tests by default when shipped. A1899:3-17; A7055-58; A12139; A12148; A12220; A12361-63; A10878. Mr. Boucher further testified that Zoll's customers "use the accused products as they were intended to be used." A1899:22-A1900:5; A2483:5-16. And when those customers purchase Zoll's defibrillators, the defibrillators perform self-tests.

c. Evidence of No Noninfringing Uses

Philips established at trial that Zoll's defibrillators have no noninfringing uses. Philips's expert, Dr. Wolf, testified that when Zoll's defibrillators are used as intended, they provide electrotherapy to the patient and do not have a

noninfringing use. A1688:13-A1689:4. He explained that the only shocks Zoll's defibrillators can deliver are infringing waveforms. A1688:18-20. Dr. Wolf further testified that Zoll's defibrillators are adapted for use in performing the methods of the waveform patents because "that's what they were built to do." A1688:21-A1689:1. He explained that they "were manufactured for the purpose of delivering shocks and delivering the specific shocks that the device delivers." A1699:1-4. The specific shocks that Zoll's defibrillators deliver carry out the claimed steps of the waveform patents. A1688:18-20. Zoll identified no noninfringing use for its defibrillators at trial.

For the self-test patents, Zoll configures its defibrillators to run self-tests by default when shipped (A7055-58; A12139; A12148; A12220; A12361-63; A10878), and these tests run automatically (A1841:8-A1843:24). No other use for this circuitry was identified.

B. Zoll's '526 Patent

1. Patent Overview

The '526 patent is directed to a "combined defibrillation and pacing electrode." A343. As described in the patent's "Background of the Invention," defibrillation electrodes are used to perform cardiac defibrillation. A346 at 1:8-18. Defibrillation sends a "high energy electrical pulse" through a patient's skin "to a patient's fibrillating heart to resynchronize the heart's pulse generators." *Id.* at

1:12-15. This electrical pulse is sent from a defibrillator to a patient "via a pair of electrodes applied to the patient's thorax." *Id.* at 1:19-22.

These electrodes consist of a flexible backing that supports a conducting plate. *Id.* at 1:28-30. A gel layer is used on top of the electrode. *Id.* at 1:34-46. This gel provides a contact surface between the skin and the conducting plate. *Id.* Generally, the gel is water based, causing the gel to soak into the skin and provide a conducting path for the defibrillation pulse. *Id.* This type of electrode is shown in Figure 2B of the '526 patent above. A345. The "resistance" or impedance of the electrode gel determines how much of the defibrillation pulse is dissipated into the gel. A346 at 1:47-56. A gel with a lower resistance will have less energy dissipated into the gel and more energy delivered into the body. *Id.* Conversely, a gel with a higher resistance will have more energy dissipated into the gel and less energy delivered into the body. *Id.* at 1:47-56, 2:36-44.

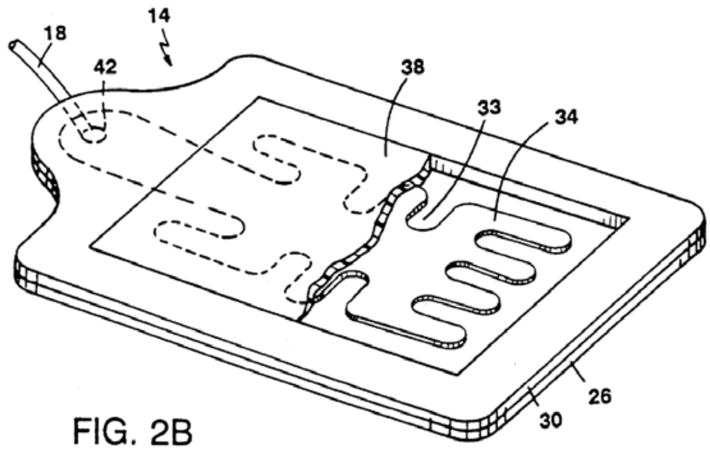

FIG. 2B

The '526 patent states that its "invention" involves "increasing the resistance of electrodes." *Id.* at 2:16-18. It asserts that, by increasing resistance, the "potential for burning of the skin during the defibrillation" decreases. *Id.* at 2:18-

20. In particular, the ’526 patent asserts that the “invention provides an electrode gel resistance which is high enough to significantly decrease the potential for burning of a patient’s skin” and is also “low enough that only an insignificant percentage of the defibrillation pulse is dissipated in the gel resistance.” *Id* at 2:36-44.

To determine whether the resistance of a particular gel is “high enough,” the ’526 claims set forth the following test to measure that resistance:

> [A] layer of electrolytic gel comprising a concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a 50 Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than 1 Ω when a 200 Joule defibrillation pulse is discharged into the series circuit . . . .

A350-51 at claims 1, 24, 32. More simply, two electrodes are placed facing each other so that their gel layers are touching. A349 at 7:50-53. A defibrillation pulse (or shock) is then delivered through the electrodes, and the resistance of the electrode is measured. *Id.* at 7:53-8:3. If the measured resistance is greater than 1 Ω,[4] it is “high enough” to meet the claims. A350-51 at claims 1, 24, 32. If the resistance is 1 Ω or less, it is not “high enough.” *Id.*

[4] An “ohm” or “Ω” is the standard unit for measuring electrical resistance.

2. Trial on Indefiniteness

At trial, Philips asserted that the ’526 claims are indefinite. Although the claims generally recite a test for an electrode, the ’526 patent never discloses a number of factors that can affect the outcome of that test. Specifically, the patent never discusses (1) at what temperature to perform the test, (2) how many defibrillation pulses or “shocks” should be used, or (3) at what age the electrode should be tested. A2114:16-A2115:9; A2334:21-A235:17; A5066:24-A5067:22.

a. Temperature Affects the Test Results

It is undisputed that the ’526 patent does not disclose the temperature at which an electrode should be tested. A2114:16-20; A2334:21-A2335:1; A5066:24-A5067:22. Instead, Zoll’s expert testified that the tests should be carried out at “room temperature,” which he acknowledged was guided by an industry standard that “[a]ll tests shall be performed at 23 plus or minus 5 degrees Centigrade.” A5159:1-21; A2334:21-A2335:4. Of this 18ºC to 28ºC range, he testified that “certainly those are all room temperatures.” A5155:9-13. Because of this, he testified that one would have known to test at any temperature within this range.[5] A5159:1-23.

[5] Philips’s expert testified that a person skilled in the art could test the electrode at any temperature in the range of 15ºC to 35ºC. A5071:2-A5072:4. For this appeal, however, Philips assumes that this issue was resolved in Zoll’s favor.

Philips's expert explained that an electrode's resistance can vary significantly at different temperatures. A5067:4-14. With an increase in temperature, the electrode's resistance will generally decrease. A5067:23-A5068:21. And, thus, a decrease in temperature will lead to an increase in the electrode's resistance. *Id.* This was confirmed by a Philips engineer who has tested ten to twenty thousand electrodes throughout the course of his work. A5012:11-A5013:16.

To demonstrate the effect temperature has on resistance, Philips's expert ran a number of experiments. First, he tested whether the energy level used has a significant effect on the measured resistance.[6] A5073:9-A5074:4. The results, shown below, demonstrated very little variance due to the energy level.

	100 Joules	150 Joules	200 Joules	360 Joules
Test 1	1.75 Ω	1.76 Ω	1.63 Ω	1.64 Ω
Test 2	1.68 Ω	1.69 Ω	1.66 Ω	1.64 Ω

A12101-09; A5073:9-A5074:4.

[6] This energy level experiment was run because the equipment that was used to test electrodes at varying temperatures used 150 joule shocks, whereas the '526 patent discloses using 200 joule shocks. A12011-50; A350-51. Based on the results of this test, Philips's expert confirmed that the energy level used did not significantly affect the measured resistance. A12101-09; A5073:9-A5074:4.

Next, Philips's expert tested an electrode model at different temperatures within the 18ºC to 28ºC temperature range suggested by Zoll's expert. A12110; A12011-50. As shown below, the resistance varied dramatically depending on the temperature at which the electrode was tested.

	18ºC	23ºC	28ºC
Test 1	1.36 Ω	1.11 Ω	0.92 Ω
Test 2	1.51 Ω	1.27 Ω	1.13 Ω

A12110; A12011-50. The tests showed that the resistance of a particular electrode can increase nearly 50% as the temperature decreases. A12110; A12011-50. Thus, testing an electrode at 28ºC could yield a resistance of less than 1 Ω (not infringing) while the same electrode tested at 18ºC could yield a resistance of over 1 Ω (infringing). A12110; A12011-50; A5140:22-A5041:10. Because the infringement determination can be manipulated by adjusting the temperature of the test, Philips's expert testified that one could not determine the scope of the claims. A5083:1-22; A5066:2-A5067:14; A5074:5-A5075:21.

Zoll's expert did not dispute this testing.[7] And he did not dispute that the test recited in the claims could lead to both infringing and noninfringing results due

[7] Zoll's expert conceded that he tested at one temperature (approximately 70-72ºF or 21-22ºC). A2337:22-A2338:2.

to changes in temperature, stating "[y]ou could certainly have an electrode that that could happen to." A5165:15-22.

b. The Number of Shocks Affects the Test Results

It is also undisputed that the '526 patent does not disclose over how many defibrillation shocks the electrode should be tested. A2115:3-6; A2335:8-13; A5066:24-A5067:22. Zoll's expert testified that one could use any number up to ten shocks on an electrode.[8] A2354:7-17. But Philips's expert explained that the number of shocks used is another important condition that strongly affects the resistance of an electrode. A5066:24-A5067:14.

To illustrate the effect that shocks can have on an electrode's resistance, Philips's expert discussed testing that Zoll performed. A5078:15-A5080:5. During the litigation, Zoll tested Philips's Pediatric Plus Multifunction Electrode Pads. A11321-22; A5078:15-A5080:5. As shown below, the results of those tests varied based on the number of shocks used.

Shock Number	Electrode #1	Electrode #2
1	0.957 Ω	0.923 Ω
2	0.989 Ω	0.947 Ω

[8] Philips's expert testified that one could test an electrode up to twenty-five times. A5077:24-A5078:11. For this appeal, however, Philips assumes that this issue was resolved in Zoll's favor.

3	1.02 Ω	0.959 Ω
4	1.08 Ω	0.972 Ω
5	1.14 Ω	0.984 Ω
6	1.19 Ω	1.00 Ω
7	1.23 Ω	1.01 Ω
8	1.29 Ω	1.03 Ω
9	1.30 Ω	1.04 Ω
10	1.32 Ω	1.06 Ω

A11321-22. In the first test, the resistance of the electrode increased nearly 40% over the course of ten shocks. *Id.* For the first two shocks, the electrode's resistance was below 1 Ω (noninfringing), whereas for the third through tenth shocks it was above 1 Ω (infringing). *Id.* Similarly, in the second test, the electrode's resistance was at or below 1 Ω (noninfringing) for the first six shocks, but over ten shocks it continued to rise above 1 Ω (infringing). *Id.*

When questioned about these results, Zoll's expert could not say whether an electrode infringed, testifying that, "[f]or this particular electrode there would be a contention." A2349:14-A235022. His only response was that he had not accused that particular electrode of infringement. A2352:3-7. But as Philips's expert explained and the tests results show, the test can either result in a resistance that falls outside the claim or within the claim, depending on the number of shocks. A5079:17-A5080:5.

c. The Age of an Electrode Affects the Test Results

The ’526 patent also does not disclose at what age the electrode should be tested. A2114:24-A2115:2; A2335:5-7; A5066:24-A5067:22. And it was undisputed that one could test the electrode at any point within its shelf life. A2353:17-21; A5081:11-19. But Philips’s expert noted that, even within an electrode’s shelf life, its age can affect resistance. A5081:3-A5082:3. He explained that an electrode’s gel is primarily water, which can evaporate over time and cause an increase in resistance. *Id.* Thus, an electrode with a typical two-year shelf life can have its resistance substantially increase with age, even before expiration. *Id.*

Philips’s expert discussed tests that Zoll conducted to show the impact that aging had on one of its electrode models. *Id.*; A11292. As shown below, the electrode’s resistance increased significantly after it was aged for just one year.[9]

Nominal Values	Aged for 12 Months
1.4 Ω	2.0 Ω

[9] The test report refers to the “impedance” of the electrode. A11292. The terms “impedance” and “resistance” are often used interchangeably. A5067:4-6.

A11292. Thus, having aged only a year, the resistance of the electrode increased over 40%. *Id.* And, again, Zoll's expert did not dispute this testing, agreeing instead that an electrode's resistance could increase with age. A2347:3-10.

d. The Jury's Instructions, the Verdict, and Post-Verdict Motions

Over Philips's objection (A5340:18-A5341:7), the district court instructed the jury that "*only* claims that are insolubly ambiguous are indefinite." A5336:6-16 (emphasis added). Zoll also emphasized the "insolubly ambiguous" standard to the jury in its closing:

> And Zoll's patent is valid unless it's either insolubly ambiguous or it would require what's called "undue experimentation" in order to put it into practice.

A5217:21-24. In light of this instruction, the jury found that the claims of the '526 patent were not invalid. A116. Philips then moved for judgment as a matter of law or a new trial, which the district court denied without explanation. A7.

3. The District Court Excluded Prior Art

At trial, Philips sought to introduce two pieces of prior art to the '526 patent, both of which disclose and describe an electrode having a resistance greater than 1 Ω. A5621; A5673. One was a prior-art electrode—the Marquette Responder 1200 electrode—that was sold by Marquette Electronics in the early 1990s. A5684:14-A5685:6; A5687:18-A5689:14; A5676-79. In connection with this

electrode, Philips sought to introduce the Marquette Electronics 510(k), which described the electrode. A5629-75.

The other piece of prior art was a Physio-Control Fast-Patch 510(k) application. A5585-628. The Physio-Control 510(k) was accessible to the public and had been obtained through the Freedom of Information Act ("FOIA"). A5586. The district court excluded both 510(k) applications, holding that "such notifications are not prior art under the Patent Act." A5005:2-11.

IV. SUMMARY OF ARGUMENT

The district court erroneously denied Philips's motion for judgment as a matter of law that Zoll contributes to its customers' infringement of the waveform and self-test patents. Contributory infringement under 35 U.S.C. § 271(c) requires that: (1) there is direct infringement; (2) the accused infringer had knowledge of the patent; (3) the component has no substantial noninfringing uses; and (4) the component is a material part of the invention. *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010). There is no legally sufficient basis under any of these elements to support the jury's verdict.

The jury found that Zoll's defibrillators directly infringed the asserted waveform and self-test patent claims. A105-11. And the unrebutted evidence established that customers use Zoll's defibrillators to execute each step of the

waveform and self-test claims. Zoll's own witness testified that customers use Zoll's defibrillators as intended.

Philips's unrebutted evidence also established that Zoll knew of the waveform and self-test patents and its infringement by 2008, when Philips began sending letters to Zoll detailing its infringement. Zoll's infringement was so obvious that Zoll did not even bother to deny infringement of the self-test patents. In light of such explicit warnings and actions on Zoll's part, there is no legally sufficient basis for a jury to determine that Zoll did not know of the self-test patents or their infringement. As for the waveform patents, after Philips pointed to Zoll's website as proof that its defibrillators infringed, Zoll deliberately changed the website's description of its defibrillators—but not the devices themselves. Zoll's blatant attempt to disguise how its defibrillators operate is unrebutted evidence that Zoll both knew of the waveform patents and knew it was infringing.

The unrebutted evidence also established that there are no noninfringing uses for the defibrillation and self-test features in Zoll's defibrillators. While Zoll's defibrillators can also perform pacing and monitoring, the self-test and defibrillation features are separate and distinct functions. Zoll cannot avoid contributory infringement "merely by embedding" its infringing self-tests and waveforms as components "in a larger product with some additional, separable feature." *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1337 (Fed. Cir.

2008). There is no use for the defibrillation and self-test features in Zoll's defibrillators other than delivering infringing waveforms and performing infringing self-tests. Likewise, the evidence established that the defibrillation and self-test features in Zoll's defibrillators are material to the claimed inventions because they automatically execute each and every element of the infringed claims. Accordingly, this Court should reverse the district court's refusal to find contributory infringement as a matter of law.

For Zoll's '526 patent, the evidence at trial showed that the claims are indefinite. Each '526 claim recites a vague test whose results can vary based on a number of conditions that the patent fails to disclose. This leads to a zone of uncertainty as to what the claims cover and what is infringement. Indeed, manipulating these undisclosed conditions can turn a noninfringing electrode into an infringing electrode. A product that can both infringe and not infringe based on undisclosed conditions is the epitome of indefiniteness. *See Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003). Thus, this Court should reverse the district court's refusal to hold the claims invalid.

If this Court does not hold the '526 claims invalid for indefiniteness, it should order a new trial on validity. The district court gave the jury an erroneous instruction, telling the jury that "only" claims that are insolubly ambiguous are indefinite. Also, the court improperly excluded prior art based only on its form.

When properly considered, an electrode, along with documents describing that electrode, and a publicly available 510(k) are prior art and should not have been excluded.

V. ARGUMENT

A. Standard of Review

This Court "reviews a district court's denial of judgment as a matter of law according to regional circuit law." *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1356 (Fed. Cir. 2011). In the First Circuit, "[t]he district court's decision to grant or deny a motion for judgment as a matter of law is reviewed de novo." *Soto-Lebron v. Fed. Express Corp.*, 538 F.3d 45, 56 (1st Cir. 2008). Judgment as a matter of law is warranted when "the presentation of the party's case reveals no 'legally sufficient evidentiary basis' for a reasonable jury to find for that party." *Mag Jewelry Co. v. Cherokee, Inc.*, 496 F.3d 108, 117 (1st Cir. 2007) (quoting Fed. R. Civ. P. 50(a)(1)).

"[A] determination of whether a claim recites the subject matter which the applicant regards as his invention and is sufficiently definite, so as to satisfy the requirements of 35 U.S.C. § 112, ¶ 2, is a legal conclusion that is reviewed de

novo." *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338 (Fed. Cir. 2003).[10]

The denial of a motion for a new trial is reviewed under the law of the regional circuit. *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1365 (Fed. Cir. 2013). In the First Circuit, a "challenge[] [to] the district court's jury instructions . . . engenders de novo review." *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64, 67 (1st Cir. 2014). "Whether a jury instruction on an issue of patent law is erroneous is a matter of Federal Circuit law that is reviewed de novo." *Commil*, 720 F.3d at 1365.

Evidentiary rulings are also reviewed under the law of the regional circuit. *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004). In the First Circuit, such rulings are generally reviewed for abuse of discretion. *United States v. Souza*, 749 F.3d 74, 84 (1st Cir. 2014). But "where a district court rules, as a matter of patent law, that a party is precluded from introducing evidence," this Court applies de novo review. *Sulzer*, 358 F.3d at 1363. Moreover, "a material error of law constitutes a per se abuse of discretion." *R & G Mort. Corp. v. Fed. Home Loan Mort. Corp.*, 584 F.3d 1, 8 (1st Cir. 2009).

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[10] Because the jury found the '526 patent claims are not invalid, Philips's appeal assumes that all underlying facts were found in Zoll's favor.

B. Philips's Unrebutted Evidence Established that Zoll Is a Contributory Infringer of the Waveform and Self-Test Patents

At trial, Philips provided unrebutted evidence proving the four elements of contributory infringement: (1) direct infringement; (2) Zoll's knowledge of the patents and infringement; (3) no substantial noninfringing uses of the features at issue, namely, the defibrillation features of the Zoll AED Plus, AED Pro, M Series, E Series, R Series, and X Series, and the self-test features of the Zoll AED Plus, AED Pro, and R Series; and (4) the materiality of these features to the waveform and self-test inventions. *See Fujitsu*, 620 F.3d at 1326. Conversely, Zoll did not provide substantial evidence that any of these elements were not met. *See Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1305 (Fed. Cir. 2002) (reversing the district court's denial of judgment as a matter of law that defendant induced infringement because patentee "presented evidence to support its assertion that all of the requirements for inducement were met, and [defendant] ha[d] failed to show that there is substantial evidence that any were not met").

1. Zoll and Its Customers Directly Infringe the Waveform and Self-Test Patents

Philips proved at trial that Zoll's defibrillators using the biphasic waveform directly infringed the waveform patents. A14582-85; A2456:10-A2459:15; A1630:17-A1634:23; A1635:1-A1668:15; A1670:8-A1673:20. Philips also established that Zoll's customers infringed when they use Zoll's defibrillators to

defibrillate. Zoll's own witness testified that its customers use Zoll's defibrillators as they were intended to be used—to defibrillate. A1899:22-A1900:5; A2483:5-16.

It cannot be—and Zoll never argued—that customers never used Zoll's *defibrillators* to *defibrillate* patients. And each time customers use Zoll's defibrillators to defibrillate, they use Zoll's biphasic waveform to infringe the waveform patents. A1688:18-20.

As for the self-test patents, Zoll did not dispute that its defibrillators' automatic self-tests infringed those patents. A2909:18-A2910:9. At trial, Philips showed that Zoll configures its AED Plus, AED Pro, and R Series defibrillators to *automatically* run self-tests by default when shipped, and is confident the self-test functionality is going to work as intended because of its testing. A1899:3-17; A2483:5-16; A7055-58; A12139; A12148; A12220; A12361-63; A10878. In fact, Zoll provided manuals to customers instructing them how to operate the infringing self-test features. A7055-58; A12139; A12148; A12220; A12361-63; A10878. Zoll disputed none of this evidence.

In *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009), this Court explained that "a finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." And direct infringement can be proven with circumstantial evidence.

Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1325-26 (Fed. Cir. 2009). Philips's unrebutted evidence far exceeded these minimal standards.

The jury found that Zoll's defibrillators directly infringe the waveform and self-test patents. A105-06; A108-11. In light of the unrebutted evidence concerning the use of Zoll's defibrillators, there is no legally sufficient basis for a jury to find that no customer anywhere ever used an accused Zoll defibrillator to shock a patient or that no customer ever used the self-test features, which Zoll set to run automatically.

2. Zoll Not Only Knew of the Waveform and Self-Test Patents, It Knew of Its Infringement

a. Knowledge Requirement of 35 U.S.C. § 271(c)

In *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964), the Supreme Court stated that 35 U.S.C. § 271 (c) "require[s] a showing that the alleged contributory infringer knew that the combination for which his component was especially designed was both patented and infringing."[11] The Supreme Court concluded that its "interpretation of the knowledge requirement affords Aro no defense with respect to replacement fabric sales made after January 2, 1954." *Id.* at 490. On that date, the patent holder sent a letter

[11] *See also Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011) ("[W]e proceed on the premise that § 271(c) requires knowledge of the existence of the patent that is infringed.").

identifying the patent and informing Aro of its view that Aro's conduct was infringing. *Id.* at 489-90. The Supreme Court treated the patent owner's communication as establishing Aro's knowledge for § 271(c). *Id.* at 489-91. Put differently, the Supreme Court focused not on whether Aro subjectively believed that its conduct was infringing, but on whether Aro had been given adequate warning of the risk of infringement.

Similarly, this Court stated that § 271(c) makes clear that "only proof of a defendant's *knowledge*, not *intent*, that his activity cause infringement [is] necessary to establish contributory infringement." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990). The intent needed for contributory infringement is "minimal," requiring no more than knowledge of a patent and knowledge that the component was especially made or adapted for use in an infringing manner. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006) (en banc in part); *see also Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) (explaining that § 271(c) "was devised to identify instances in which it may be *presumed* from distribution of an article in commerce that the distributor intended the article to be used to infringe another's patent, and so may justly be held liable for that infringement" (emphasis added)). Philips's evidence was clear and unrebutted that Zoll knew of the waveform and self-test patents for many years, and knew of infringement by 2008.

b. Zoll Knew It Infringed the Waveform and Self-Test Patents When Philips Told It So

Zoll did not dispute that it knew of the self-test and waveform patents years before Philips filed this suit. Zoll's CEO, Mr. Packer, testified that he was aware that Philips was litigating with other companies on the waveform and self-test patents as far back as 2003. A1983:1-24. Mr. Packer testified that "[t]his is a small industry. There are three main players. We all know what each of us are doing. We track each other very, very closely." A1965:22-A1966:22. The '454 waveform patent was even cited in some of Zoll's patents issuing as early as 1998. A8489; A14774; A18039; A18064; A18084; A1984:5-A1985:23; A1751:19-A1752:14.

Zoll's knowledge of infringement was cemented at least by 2008, when Philips sent notice letters describing Zoll's infringement of the waveform and self-test patents. A1958:24-A1959:11; A1978:21-A1979:10; A1980:18-A1981:18; A12706-13. Philips's letters to Zoll were more than blanket accusations—they included specific evidence of infringement. A12706-13; A1979:1-A1980:1. For instance, a 2009 letter pointed to Zoll's own website as proof that its defibrillators infringed the waveform patents. A12706; A1980:18-A1981:3. At the time, Zoll's website openly acknowledged that its products measured impedance "[d]uring the first 250 microseconds of a shock delivery," thereby satisfying the "during the discharging step" of the waveform claims. A8432-33 (emphasis added); *see also*

A1981:17-A1982:25; A376 at 14:47-60; A391 at 18:17-39. That is, Zoll's website detailed how Zoll's defibrillators practiced each element of the waveform claims.

On receiving Philips's letters, Zoll knew it had an infringement problem. But rather than confront that problem, Zoll tried to hide it by deliberately changing its website to instead read "[a]n impedance test pulse of 250 [microseconds] is applied *prior to* shock delivery." A8434-37 (emphasis added); *see also* A1981:17-A1982:25. Zoll did not, however, change how its defibrillators actually functioned. A1981:4-9; A1981:17-A1982:25; A2477:24-A2479:22. Zoll likewise did not change its self-test features and did not even deny infringement of the self-test patents at trial. A1981:4-12; A2909:18-A2910:9; A2842:9-A2843:12.

In altering its website, Zoll put the spotlight on the knowledge of infringement it was deliberately trying to disguise. Further evidencing its knowledge that it infringed the waveform patents, Zoll eventually changed when its defibrillators measure patient impedance in one of its products, but only after the close of discovery and the exchange of expert reports. A18981-86; A2453:14-A2455:1.

The Supreme Court in *Aro* found the knowledge needed for contributory infringement based on much less. *Aro*, 377 U.S. at 489-90 (finding knowledge under § 271(c) where the defendant received a letter from the patentee notifying it of the existence of the patent, and that it was "obvious" from inspection that

defendant's product would infringe); *see also Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1355 (Fed. Cir. 2010) (upholding the Commission's presumption of knowledge for contributory infringement where the patentee showed the accused infringer was aware of the patent because of license negotiations and the accused devices did not have any substantial noninfringing uses).

In sum, Zoll's own acts—altering its website to feign a change to its waveform, only to implement an actual change four years later—are clear and unrebutted evidence of Zoll's knowledge of infringement of the waveform patents. Likewise, Zoll's failure to alter its self-test feature while having no defense to infringement shows Zoll's knowledge of infringement of the self-test patents. Accordingly, there is no legally sufficient basis for a jury to find Zoll did not have knowledge of the waveform and self-test patents or their infringement.

3. Zoll's Defibrillation and Self-Test Features Have No Substantial Noninfringing Uses

Zoll's defibrillators have several features. But where an infringing feature is "separate and distinct" from the larger product it resides in, that same feature is the relevant "material or apparatus" for considering substantial noninfringing uses under § 271(c). *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 849 (Fed. Cir. 2010) (affirming jury instruction that focused on the custom XML editor, rather than all of Word, when deciding whether any noninfringing uses were

"substantial"); *see also Ricoh*, 550 F.3d at 1337 (holding that an infringer "should not be permitted to escape liability as a contributory infringer merely by embedding [the infringing feature] in a larger product with some additional, separable feature before importing and selling it"). Noninfringing uses are only substantial "when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. The defibrillation and self-test features in Zoll's defibrillators are separate and distinct from other features and are suitable only for infringing uses.

a. Zoll's Defibrillation Feature Has No Substantial Noninfringing Uses

The main purpose of Zoll's defibrillators is to defibrillate a person suffering from cardiac arrest. Every time Zoll's defibrillators shock a patient, they perform the method claimed in the waveform patents. A1688:18-20. Zoll's accused defibrillators cannot deliver a shock to a patient in a way that does not infringe the waveform patents. While Zoll later changed one of its defibrillators so it no longer used the claimed method, none of the accused defibrillators found to infringe could deliver a shock in a noninfringing way.

To the extent Zoll contends its defibrillators have noninfringing functionalities, such as monitoring a patient's heart rhythm,[12] those functionalities are not at issue. None of those additional features involves Zoll's biphasic waveform and defibrillation method, which was a separate and distinct addition to Zoll's defibrillators. A1951:16-23 (testimony of Mr. Packer, noting that Zoll's M-Series defibrillator first included a monophasic waveform in 1998, which was later replaced with a biphasic waveform in 1999). Like the specific features in *Fujitsu*, *i4i*, and *Lucent*, the defibrillation feature in Zoll's defibrillators is separate and distinct from any other functionality and should be the focus of the contributory infringement analysis. *See, e.g.*, *Fujitsu*, 620 F.3d at 1330-31; *i4i*, 598 F.3d at 851-52; *Lucent*, 580 F.3d at 1320-21.

Here, there is no evidence that Zoll's defibrillation feature has substantial noninfringing uses, and for good reason. The defibrillation feature is used for one purpose only—to shock patients. And when the defibrillators shock patients, they follow the claimed method. A1688:13-A1689:4; A14582-85; A2456:10-A2459:15. Zoll did not refute or rebut this evidence.

[12] Although no Zoll witness testified about any alleged noninfringing uses for the accused defibrillators, Zoll's counsel argued in closing that "Zoll's products do many, many other things other than deliver defibrillation," and identified "pacemaking," "monitoring," and "blood oxygen sensing." A5231:16-19. No evidence supported Zoll's attorney argument, but in any event those functions are separate and distinct and not at issue here.

For these reasons, there is no legally sufficient basis for a jury to find that the defibrillation feature in Zoll's defibrillators has substantial noninfringing uses.

b. Zoll's Self-Tests Have No Substantial Noninfringing Uses

For the self-test patents, the features at issue are the specific hardware and software that perform infringing self-tests. *See Fujitsu*, 620 F.3d at 1330-31 (holding that "the component at issue [was] the specific hardware and software that performs [sic] fragmentation," not the larger "fragmentation threshold tool"). Zoll's CEO testified that adding the "automatic self-testing" features (i.e., the periodic self-tests before power on) into its defibrillators enabled Zoll to enter the public-access defibrillator market. A1943:11-21. These automatic self-tests were separate and distinct from the self-tests that Zoll had previously included in its defibrillator, which all required user involvement, and should be the focus of the contributory infringement analysis.

To that point, there is no evidence that Zoll's self-test features have substantial noninfringing uses. Zoll pursued no noninfringement theory for the self-test patents at trial and failed to identify a noninfringing use for the automatic, periodic self-test feature in its defibrillators. Zoll configures its defibrillators to run self-tests by default when shipped, and customers use those defibrillators to perform self-tests in an infringing manner. A1899:3-A1900:5; A7055-58; A12139; A12148; A12220; A12361-63; A10878. Including the self-test feature

within larger defibrillators does not change the self-test features' admittedly infringing use. *See Lucent*, 580 F.3d at 1321 (affirming that the date-picker feature included in Outlook was suitable only for an infringing use, even though Outlook itself had many noninfringing uses).

For these reasons, there is no legally sufficient basis for a jury to find that the self-test features in Zoll's defibrillators have substantial noninfringing uses.

4. The Defibrillation and Self-Test Features in Zoll's Defibrillators Are Material to the Inventions

Zoll's defibrillation (i.e., waveform) circuitry is a material part of the invention claimed in the waveform patents. A1689:5-7. Zoll's defibrillators automatically perform each step of the asserted method claims in the waveform patents every time a shock is delivered. In other words, the defibrillation circuitry in Zoll's defibrillators is not just material to the claimed waveform invention—it automatically executes each step. Likewise, the self-test features in Zoll's defibrillators are a material part of the invention claimed in the self-test patents for one simple reason—they automatically execute each and every element of the applicable self-test claims. A1842:8-A1850:11; A1854:5-A1857:19; A1860:10-A1864:17; A106.

Thus, there is no legally sufficient basis for a jury to find that the defibrillation circuitry and self-test features in Zoll's defibrillators are not material to the claimed inventions, especially where they automatically execute each and

every claim element. And because there is no legally sufficient basis for a jury to find that any of the elements of contributory infringement are not met, judgment of contributory infringement of the waveform and self-test patents should be entered.

C. Judgment that Zoll's '526 Patent Is Not Invalid Should Be Reversed

Under 35 U.S.C. § 112, ¶ 2, "a patent must be precise enough to afford clear notice of what is claimed, thereby 'appris[ing] the public of what is still open to them.'" *Nautilus, Inc. v. Biosig Instruments, Inc.* 134 S. Ct. 2120, 2129 (2014) (alteration in original) (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996)). Without that precision, "there would be '[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Id.* (alteration in original) (quoting *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942)). To avoid this "zone of uncertainty," the Supreme Court held that "a patent is invalid for indefiniteness if its claims, read in light of the specification . . . and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 2124.

Here, the scope of the '526 claims cannot be determined with reasonable certainty. While the claims recite testing the resistance of an electrode, the patent does not disclose the test conditions despite that these conditions greatly impact the measured resistance. The only evidence presented at trial was that an accused electrode can be both infringing and noninfringing depending on (1) the

temperature at which the electrode is tested, (2) the number of shocks the electrode is subjected to, and (3) the age of the electrode. This Court has declared situations like this, where a product "might infringe or not depending on its usage in changing circumstances," "the *epitome of indefiniteness*." *Geneva Pharm.*, 349 F.3d at 1384 (emphasis added).

A competitor could measure the resistance of the electrode and determine that it is less than 1 Ω and not infringed. But the patentee could later manipulate the test conditions by decreasing the temperature, increasing the number of shocks, or waiting until the electrode had aged to obtain the resistance it wanted. This creates precisely the zone of uncertainty the Supreme Court warned against.

1. The Claimed Resistance Varies Based on Undisclosed Conditions, Including Temperature, Number of Shocks, and Age of the Electrode

The '526 patent does not disclose the temperature at which the claimed electrode must be tested even though this condition can be dispositive of the measured resistance. A2114:16-20; A2334:21-A2335:1; A5066:24-A5067:22. Zoll's expert urged that a person skilled in the art would know to test an electrode at room temperature, which he acknowledged could encompass any temperature within the 18ºC to 28ºC range. A5159:1-21; A5154:20-A5155:22. But the evidence also showed that testing the electrode at different temperatures within the

"room temperature" range produced significantly different results. A12110; A12011-50.

While testing an electrode at the higher end of the room-temperature range produced a noninfringing result (less than 1 Ω), testing the *same electrode* at the lower end of the room-temperature range produced an infringing result (greater than 1 Ω).[13] A12110; A12011-50. Thus, an electrode can be either infringing or noninfringing based on whether one chooses to test the electrode in a warmer or colder room. Even Zoll's expert agreed that "[y]ou could certainly have an electrode that that could happen to." A5165:15-22.

Like temperature, the '526 patent makes no mention of how many shocks to deliver when carrying out the claimed test. A2115:3-6; A2335:8-13; A5066:24-A5067:22. Zoll's expert asserted that any number of shocks up to ten could be delivered. A2354:7-17. And the evidence showed that the number of shocks can be a pivotal factor in determining whether an electrode infringes. A5078:15-A5080:23. In two tests Zoll performed, the electrodes produced noninfringing results for the first few shocks (less than 1 Ω), but the results became infringing as

[13] Multiple tests showed an increase of approximately 0.4 Ω over this temperature range, which is a substantial increase when a product need only reach 1 Ω to infringe. A12110; A12011-50.

the number of shocks increased to ten (greater than 1 Ω).[14] A11321-22; A5078:15-A5080:23. Thus, even in the range of shocks suggested by Zoll's expert, the claimed test can produce infringing and noninfringing results based on the number of shocks chosen. A11321-22; A5078:15-A5080:23.

The '526 patent also does not mention the age at which the electrode should be tested. A2114:24-A2115:2; A2335:5-7; A5066:24-A5067:22. And it was undisputed that one could test an electrode at any point in its normal shelf life, which is generally two years. A2353:17-21; A5081:11-19. But the evidence also showed that the age of an electrode greatly impacts its resistance. A5081:2-A5082:3. Indeed, testing that Zoll itself had done showed that after only one year (half of the average shelf life), the resistance of an electrode can increase over 40%. A11292; A5081:20-A5082:25. Philips's expert testified that this increase is caused by water evaporating from the electrode gel over time. A5081:4-A5082:3. He explained that, over the long shelf life of these products, this water loss can substantially increase an electrode's resistance. A5081:2-10. Zoll's expert did not disagree, testifying that the resistance could increase as the electrode aged. A2347:5-10.

[14] One test showed an increase of over 0.36 Ω over the course of ten shocks. A11321.

Thus, the undisputed evidence showed that temperature, number of shocks, and age all greatly impact an electrode's measured resistance. Yet neither the '526 claims nor the patent itself identifies what conditions should be used. While Zoll's expert testified that one would know to test at one of a *range* of temperatures (18ºC-28ºC), to test over a *range* of shocks (up to 10), and to test at one of a *range* of electrode ages (any time within the shelf life) (A5154:23-A5059:21; A2353:17-A2354:17), Zoll presented no evidence on how a skilled person could discern the scope of the claims while still allowing for a range of outcome-altering test conditions.

2. The Scope of the '526 Claims Is Not Reasonably Certain, Making Them Indefinite

Zoll chose to claim its invention through a vague test. But the '526 patent's failure to identify many of the test conditions—any one of which could mean the difference between infringement and noninfringement—makes the scope of its claims not reasonably certain. While "[t]he primary purpose of the definiteness requirement" is to ensure that "competitors of the patent owner[] can determine whether or not they infringe," *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002), the '526 claims have frustrated that purpose and created the very "innovation-discouraging 'zone of uncertainty'" that the Supreme Court cautioned against. *Nautilus*, 134 S. Ct. at 2130 (quoting *United Carbon*, 317 U.S. at 236).

A person skilled in the art would be unable to discern with any reasonable certainty whether its electrode infringed, as the outcome of the claimed test can be manipulated merely by adjusting the temperature, the number of shocks, or the age of the electrode. A5066:24-A5067:22; A5083:23-A5084-10. Even if a competitor were to test his electrode and find the resistance was less than 1 Ω (and thus noninfringing), it could not be certain that the patentee could not manipulate the test conditions to accuse it of infringement. Thus, a competitor attempting to enter the market could "enter only at the risk of infringement claims"—subject to the vagaries of the '526 patent's ambiguous test. *Nautilus*, 134 S. Ct. 2129 (quoting *United Carbon*, 317 U.S. at 236).

Even under the previous, more demanding "insolubly ambiguous" standard, this Court has held claims similar to those in the '526 patent to be indefinite. For example, *Halliburton Energy Services, Inc. v. M-I LLC* involved a patent on "fragile gels" used in oil-field drilling. 514 F.3d 1244, 1246 (Fed. Cir. 2008). At issue was whether the claims were indefinite under Halliburton's proposed construction for the term "fragile gel." *Id.* at 1250. This Court held the claims were indefinite because "an artisan would not know from one well to the next whether a certain drilling fluid was within the scope of the claims because a wide variety of factors could affect [infringement]." *Id.* at 1254-55. In other words, "a given fluid" might be infringing "in some formations and/or well configurations,

whereas in others it would not be." *Id.* The Court emphasized the problem with these disparate results, noting that, "[w]hen a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite." *Id.*

As in *Halliburton*, if an electrode infringes when tested in one environment but not in another, the '526 claims are indefinite. *Id.* While Zoll's expert testified that one would know to test an electrode at any temperature within the 18ºC-28ºC range, "[t]he fact that an artisan would know how to perform these measurements and tests . . . says nothing about whether the artisan would also know which" electrodes are infringing. *Id.* at 1254. Because neither the '526 patent nor the standard suggested by Zoll's expert discloses a *specific* temperature to conduct the test, a skilled person may test an electrode in either a colder or warmer room, which can result in different infringement determinations. A12110. Likewise, a skilled person could test an electrode using one shock or more shocks, which can also result in different infringement determinations. This type of claim, which would require one to "make a separate infringement determination for every set of circumstances in which the [product] is used," is indefinite. *Halliburton*, 514 F.3d at 1255.

In *Geneva Pharmaceuticals*, this Court similarly cautioned that claims allowing for inconsistent infringement determinations are indefinite. 349 F.3d at 1384. There, the issue was whether a drug contained a "synergistically effective amount" of certain chemicals to effect treatment against bacteria. *Id.* The patentee argued that a drug formulation would fall outside the claims if it did not have activity against a bacterium. *Id.* The court rejected that as indefinite, noting that under this construction, "a formulation . . . might infringe or not depending on its usage in changing circumstances." *Id.* Indeed, it noted that "a given embodiment would simultaneously infringe and not infringe the claims, depending on the particular bacteria chosen for analysis. Thus, one skilled in the art would not know from one bacterium to the next whether a particular composition standing alone is within the claim scope or not. That is the epitome of indefiniteness." *Id.* The situation here is no different. For instance, depending on whether an electrode is tested in a colder or warmer room, with one shock or ten shocks, or when it is made or a year or two later, the electrode "might infringe or not depending on its usage in changing circumstances." *Id.* This is the "epitome of indefiniteness." *Id.*

Likewise, this Court's decision in *Honeywell* shows the indefiniteness of the '526 claims. 341 F.3d at 1335. There, the claims required measuring the "melting point elevation" to produce yarn. *Id*. Yet the specification did not disclose a method to prepare the materials necessary for that measurement, despite that "the

sample preparation method [was] critical in determining" the melting point elevation. *Id*. at 1335, 1341. Indeed, the Court found that "the testing results will necessarily fall within or outside the claim scope depending on the sample preparation method chosen." *Id.* at 1341. The Court explained that "[c]ompetitors trying to practice the invention or to design around it would be unable to discern the bounds of the invention" and held that the claims were indefinite as insolubly ambiguous. *Id.* Here, the '526 patent also does not disclose the test conditions even though they are necessary to determine whether an electrode falls within or outside the claim. As a result, the '526 claims would have failed to pass scrutiny under this Court's prior "insolubly ambiguous" standard, and they certainly fail to provide "reasonable certainty" of their scope as required by the Supreme Court. *Nautilus*, 134 S. Ct. at 2124.

Because infringement can be manipulated by the patentee, the claims of the '526 patent have foiled one of the primary purposes of the definiteness requirement, which is "to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights." *Halliburton*, 514 F.3d at 1249 (alteration in original) (citation omitted). The "claims . . . allow [Zoll] to benefit from the ambiguity, rather than requiring [Zoll] to give proper notice of the scope of the claims to competitors." *Id.* at 1254. This Court has rejected such ambiguous claims, as they can "retard innovation because

cautious competitors may steer too far around that which [the patentee] actually invented." *Id.*

Here, a cautious competitor could test its electrodes at the time of manufacture to ensure that their resistances were well below the infringing 1 Ω mark. Yet after only a year, those resistances could increase by 40%, causing the electrode to infringe. A11292. Likewise, the same cautious competitor could test an electrode with one or two shocks, or at 28ºC, and find its resistance below the claimed 1 Ω, only to have the patentee manipulate the number of shocks or the temperature of the room to achieve a resistance above 1 Ω. This would leave a competitor with no choice but to steer far clear of even unclaimed territory or else "enter only at the risk of infringement claims." *Nautilus*, 134 S. Ct. at 2129 (quoting *United Carbon*, 317 U.S. at 236). Thus, the claims of the '526 patent are indefinite, as they create the "zone of uncertainty" that the Supreme Court cautioned against. *Id*.

D. The District Court Legally Erred by Instructing the Jury that *Only* "Insolubly Ambiguous" Claims Are Indefinite

In *Nautilus*, the Supreme Court found that the "insolubly ambiguous" test "lack[ed] the precision § 112, ¶ 2 demands." *Id.* at 2130. "In place of the 'insolubly ambiguous' standard, [the Supreme Court held] that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the

patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* At 2124.

The district court, however, erroneously instructed the jury that the *only* test for indefiniteness was the rejected "insolubly ambiguous" standard. In particular, the court instructed the jury that, to prevail on indefiniteness, "Philips must show by clear and convincing evidence that a person of ordinary skill in the art would not understand what is and is not covered by the claims of Zoll's patent." A5336:6-16. Explaining this statement, the court said: "Absolute clarity is not necessary. Rather, *only* claims that are insolubly ambiguous are indefinite."[15] *Id.* (emphasis added). Thus, the Court instructed that the "insolubly ambiguous" test was the *only* basis for finding the claims invalid.[16]

[15] While the district court did not yet have the guidance of the *Nautilus* decision at the time of trial, it issued by the time the court denied Philips's motion for a new trial. A7. At that time, when the court denied Philips's motion for a new trial, it should have applied the current state of the law when evaluating Philips's indefiniteness challenge. *See Thorpe v. Housing Auth.*, 393 U.S. 268, 281 (1969) (stating that a court "must apply the law in effect at the time it renders its decision").

[16] Although no objection to a jury instruction is needed where an intervening change in law has made the instruction erroneous, *see Gen. Beverage Sales Co. v. East-Side Winery*, 568 F.2d 1147, 1152-53 (7th Cir. 1978), Philips objected to the district court's instruction on indefiniteness. A5340:18-A5341:7. Instead of the "insolubly ambiguous" test, Philips sought an instruction that the claims are indefinite where "they fail to put a competitor on notice of the proper scope of the claimed subject matter," which is similar to the Supreme Court's *Nautilus* test. *Id.*

Nautilus makes clear, however, that the instruction on "insolubly ambiguous" was legally erroneous. The Supreme Court held that this standard "does not satisfy the statute's definiteness requirement." *Nautilus*, 134 S. Ct. at 2124. The Court further found that the "insolubly ambiguous" standard "f[ell] short" of being "at least 'probative of the essential inquiry.'" *Id.* at 2130 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)).

The instruction was also prejudicial. Indeed, the Supreme Court emphasized that the rejected test left "courts and the patent bar at sea without a reliable compass." *Id.* The jury fared no better, as its sole criterion for determining validity was one known to "breed . . . confusion." *Id.* Moreover, the Supreme Court rejected the overly strict "insolubly ambiguous" test because it improperly "tolerate[d] some ambiguous claims but not others." *Id.* at 2124. Accordingly, the erroneous instruction forced the jury to apply too high a standard that would accept some ambiguous claims, necessarily impacting the verdict.

The prejudicial effect was also not limited to the jury instructions, as Zoll also emphasized the insolubly ambiguous standard during closing.[17] A5217:21-24 ("And Zoll's patent is *valid unless it's either insolubly ambiguous* or it would

[17] The instruction also contained other general text on definiteness. A5335-36. But the remainder of the instruction cannot cure the prejudicial effect, as the instruction makes clear that "*only* claims that are insolubly ambiguous are indefinite." A5336 (emphasis added).

require what's called 'undue experimentation' in order to put it into practice." (emphasis added)). Thus, the jury was repeatedly told that it must find the '526 claims insolubly ambiguous for Philips to prevail. Where, as here, the "instructions were legally erroneous" and "the errors had prejudicial effect," the Court "will set aside the jury verdict." *Commil*, 720 F.3d at 1365-66 (citation omitted). The Court should order a new trial on validity.

E. A New Trial Is Warranted Because the District Court Erred by Excluding Evidence of Invalidating Prior Art

The district court improperly excluded critical prior art to the '526 patent—one a prior art device and the other a printed publication. A5005:2-11. Both of these pieces of prior art relied on 510(k) FDA applications[18] for disclosures of the claimed features of the '526 patent. A5629-75; A5585-628. Rather than properly analyzing whether these references qualified as prior art, the district court instead found that there was a blanket prohibition on using 510(k) documents as prior art, holding that "such notifications are not prior art under the Patent Act." A5005:2-11. But the district court applied the wrong legal standard and improperly excluded this evidence.

[18] A 510(k) is a premarketing submission made to the FDA to demonstrate that a device is safe and effective.

1. The District Court Improperly Excluded Evidence of the Marquette Responder 1200 Electrode Prior-Art Device

Under 35 U.S.C. § 102(b), a person is not entitled to a patent if "the invention was . . . in public use or on sale in this country[] more than one year prior to the date of application for patent in the United States." The Marquette Responder 1200 electrode is a product that was sold by Marquette Electronics in the early 1990s. This was confirmed by David Schlageter, who was responsible for marketing in Marquette's defibrillator group from 1989 to 2001. A5684:14-A5685:6. He testified that, at least as of May 1990—more than one year before the '526 patent's 1992 priority date—Marquette had sold the Marquette Responder 1200 electrode in the United States. A5687:18-A5689:14. This was also corroborated by sales data contained in a Marquette Electronics sales report dated June 11, 1990. A5676-79. Thus, since the Marquette Responder 1200 Electrode was sold more than one year before the filing of the '526 patent, that product is prior art.

Rather than analyze whether the *product* qualified as prior art, the district court instead determined that FDA applications generally do not qualify as prior art. A5005:2-11. Philips explained that the "electrode itself is prior art" because there was evidence "it was sold before the '526 patent was filed" and so it was "not relying on the *publication* of the Marquette Electronics 510K" to satisfy the prior

art requirement. A5009:13-22 (emphasis added). But the district court overruled Philips's objection without explanation. A5009:13-25. The law is clear, however, that the "on-sale bar applies when, more than one year before the filing of a patent application, a product embodying . . . the patented invention was sold." *Aqua Marine Supply v. AIM Machining, Inc.*, 247 F.3d 1216, 1218 (Fed. Cir. 2001). This Court has repeatedly considered documents describing prior-art devices as relevant to how those devices function. *See Soverain Software LLC v. Newegg Inc.*, 705 F.3d 1333, 1338 (Fed. Cir. 2013) ("the CompuServe Mall system was the primary reference against the shopping cart claims, including two books *describing the system*" (emphasis added)). Because the district court improperly excluded this prior art, a new trial should be ordered.[19]

2. The District Court Improperly Excluded Evidence of the Physio-Control Fast-Patch 510(k) Application

Also under § 102(b), a "printed publication" that was publicly available before a patent application was filed is prior art to that application. It is well established that "the question to be resolved in a 'printed publication' inquiry is the extent of the reference's 'accessibility to at least the pertinent part of the public, of a perceptible description of the invention, *in whatever form it may have been*

[19] The exclusion of this evidence was prejudicial. Indeed, a document describing the Marquette 1200 electrode shows that its resistance was greater than 1 Ω, which is the element that is common to all '526 claims and that the patent asserts is critical to the invention. A5673.

recorded.'" *In re Klopfenstein*, 380 F.3d 1345, 1348 n.2 (Fed. Cir. 2004) (emphasis added) (citation omitted). Thus, the district court's exclusion of a particular *form* of document merely because it was a 510(k) submission is contrary to law. The proper inquiry is whether the document was accessible, and "[a]ccessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to." *In re Enhanced Sec. Research, LLC*, 739 F.3d 1347, 1354 (Fed. Cir. 2014) (alteration in original) (citation omitted). Despite these guiding principles, the district court excluded the Physio-Control Fast-Patch 510(k) submission, which was filed in 1987—nearly five years before the '526 patent was filed. A5588.

The relevant FDA regulations show that the Fast-Patch 510(k) was publicly available well before the '526 patent was filed. Those regulations state that, at least ninety days before a party wishes to sell a device, it must submit a 510(k) application. A5748-49 (21 C.F.R. § 807.81(a) (1991)). On final classification of the 510(k), "date and information related to safety and effectiveness of a device classified in class I (general controls) and or class II (performance standards) *shall be available for public disclosure*." A5750-51 (21 C.F.R. § 807.95(d) (1991) (emphasis added)). Additionally, "[d]ata or information submitted with, or incorporated by reference in, a premarket notification submission . . . *shall be available for disclosure* by the [FDA] when the intent to market the device is no

longer confidential." *Id*. (emphasis added). Finally, Title 21 provides a mechanism for requesting information under the Freedom of Information Act. A5564-66 (21 C.F.R. §§ 20.23, 20.30, 20.40 (1991)).

The Physio-Control Fast-Patch 510(k) application received its decision on May 20, 1987. A5588. After that, information related to the existence of the notification was made available to the public. A5750-51 (21 C.F.R. § 807.95(d)). The document itself states that the submitter (Physio-Control) requested confidentiality for only ninety days. A5589. Thus, as early as 1987, the information submitted to the FDA was "available for disclosure by the [FDA]." A5750-51 (21 C.F.R. § 807.95(d)). This is corroborated by the fact that the 510(k) document itself is accompanied by a FOIA request from 1991. A5586. That is, before the '526 patent was filed, a member of the public located and requested the Fast-Patch 510(k), showing that "the public ha[d] a means of accessing" it. *Enhanced Sec.*, 739 F.3d at 1354. This makes it prior art to the '526 patent, and its exclusion was prejudicial error warranting a new trial on validity.[20]

VI. CONCLUSION

This Court should reverse the district court's denial of judgment as a matter of law on Zoll's contributory infringement. Specifically, this Court should direct

[20] The Fast-Patch 510(k) also discloses an electrode with the critical feature of the '526 patent—a resistance of greater than 1 Ω. A5621.

the district court to enter judgment that Zoll contributed to infringement of claims 42, 67, and 68 of the ’374 patent when it sold its AED Plus, AED Pro, and R Series defibrillators; claim 7 of the ’460 patent when it sold its AED Plus and AED Pro defibrillators; and claim 51 of the ’454 patent and claims 4 and 8 of the ’905 patent when it sold its AED Plus, AED Pro, M Series, E Series, R Series, and X Series defibrillators.

This Court should also reverse the district court’s denial of judgment as a matter of law on invalidity of the ’526 patent. The scope of the ’526 claims is uncertain and subject to a vague test that can be manipulated by the patentee based on conditions that the patent fails to disclose, making the claims indefinite. If this Court does not find the claims indefinite, at the very least a new trial should be ordered due to the district court’s (1) instructing the jury that a standard rejected by the Supreme Court was the only test for indefiniteness, and (2) excluding critical prior art based on legal error.

Date: November 26, 2014

Respectfully submitted,

/s/ J. Michael Jakes

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CERTIFICATE OF SERVICE

I certify that on November 26, 2014, this Brief of Plaintiffs-Appellants Koninklijke Philips N.V. and Philips Electronics North America Corporation was filed electronically using the CM/ECF system and served via the CM/ECF system on counsel for Defendant-Cross Appellant as follows:

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/s/ J. Michael Jakes

CERTIFICATE OF COMPLIANCE

I certify that this Brief of Plaintiffs-Appellants Koninklijke Philips N.V. and Philips Electronics North America Corporation contains 13,947 words as measured by the word processing software used to prepare this brief.

/s/ J. Michael Jakes

ADDENDUM

United States District Court
District of Massachusetts

KONINKLIJKE PHILIPS N.V. and PHILIPS ELECTRONICS NORTH AMERICA CORPORATION, **Plaintiffs/ Counter-Defendants,** **v.** **ZOLL MEDICAL CORPORATION,** **Defendant/ Counter-Claimant.**	**Civil Action No. 10-11041-NMG**

ORDER OF FINAL JUDGMENT AS TO LIABILITY

In accordance with the jury verdict of December 19, 2013, it is hereby **ORDERED**:

1) Judgment shall enter in favor of plaintiffs/counter-defendants Koninklijke Philips N.V. and Philips Electronics North America Corporation (collectively, "Philips") and against defendant/counter-claimant ZOLL Medical Corporation ("ZOLL") on Count 1 of Philips's Second Amended Complaint (Docket No. 36) and on Counts 1 and 16 of ZOLL's Second Amended Counterclaim (Docket No. 38) to the extent that it is adjudged that Claim 51 of U.S. Patent No. 5,607,454 is infringed by the ZOLL AED Plus, AED Pro, R Series, E Series, M Series and X Series defibrillators and is not invalid;

2) Judgment shall enter in favor of Philips and against ZOLL on Count 4 of Philips's Second Amended Complaint and on Counts 4 and 19 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 4 and 8 of U.S. Patent No. 5,749,905 are infringed by the AED Plus, AED Pro, R Series, E Series, M Series and X Series defibrillators and are not invalid;

3) Judgment shall enter in favor of Philips and against ZOLL on Count 6 of Philips's Second Amended Complaint and Counts 6 and 21 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claim 7 of U.S. Patent No. 5,800,460 is infringed by the AED Plus and AED Pro defibrillators and is not invalid;

4) Judgment shall enter in favor of ZOLL and against Philips on Count 8 of Philips's Second Amended Complaint and Count 8 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 4 and 5 of U.S. Patent No. 5,836,978 are not infringed by the AED Plus, AED Pro, R Series, E Series, M Series and X Series defibrillators but judgment shall enter in favor of Philips and against ZOLL on Count 23 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 4 and 5 of U.S. Patent No. 5,836,978 are not invalid;

5) Judgment shall enter in favor of Philips and against ZOLL on Count 9 of Philips's Second Amended Complaint and Counts

9 and 24 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 42, 67 and 68 of U.S. Patent No. 5,879,374 are infringed by the ZOLL AED Plus, AED Pro and R-Series defibrillators and are not invalid, Claim 43 is infringed by the AED Plus, AED Pro, R Series and X Series defibrillators and is not invalid, and Claims 66 and 73 are not invalid but judgment shall enter in favor of ZOLL and against Philips to the extent that it is adjudged that Claim 66 is not infringed by the AED Plus, AED Pro, E Series and R Series and Claim 73 is not infringed by the AED Plus and AED Pro;

6) Judgment shall enter in favor of Philips and against ZOLL on Count 10 of Philips's Second Amended Complaint and Counts 10 and 25 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 1 and 5 of U.S. Patent No. 6,047,212 are infringed by the AED Plus, AED Pro, R Series and X Series defibrillators and are not invalid;

7) Judgment shall enter in favor of ZOLL and against Philips on Count 13 of Philips's Second Amended Complaint and Count 13 of ZOLL's Second Amended Counterclaim to the extent that it is adjudged that Claims 1 and 7 of U.S. Patent No. 6,356,785 are not infringed by the AED Plus, AED Pro, E Series and X Series defibrillators but judgment shall enter in favor of Philips and against ZOLL on Count 28 of ZOLL's Second Amended

Counterclaim to the extent that it is adjudged that Claims 1 and 7 of U.S. Patent No. 6,356,785 are not invalid;

8) Judgment shall enter in favor of ZOLL and against Philips on Count 1 of ZOLL's Complaint (Case 1:10-cv-11162, Docket No. 1) and Counts 1 and 6 of Philips's Counterclaim (Docket No. 13) to the extent that it is adjudged that the Philips HeartStart FR2 Infant/Child Pads, HeartStart Infant/Child Smart Pads and HeartStart Adult Smart Pads infringe Claims 1, 8, 9, 11, 12, 19, 24 and 25 of U.S. Patent No. 5,330,526; the Adult Plus MFE Electrode Pads and Multi-Function Pediatric Defibrillation Electrodes infringe Claims 1, 11, 12, 19 and 24; The HeartStart Adult Preconnect MFE Pads infringe claims 1, 9, 11, 12, 19 and 24; the Adult Radiotransparent/Reduced Skin Irritation Pads infringe Claims 1, 11, 12, 19 and 24; the Pediatric Radiotransparent/Reduced Skin Irritation Pads infringe Claims 11, 12 and 19; and Claims 1, 2, 3, 8, 9, 11, 12, 19, 23, 24 and 25 are not invalid; but judgment shall enter in favor of Philips and against ZOLL to the extent that it is adjudged that Claims 2, 3 and 23 of U.S. Patent No. 5,330,526 are not infringed by any of the aforementioned devices and Claim 1 is not infringed by the Pediatric Radiotransparent/Reduced Skin Irritation Pads;

9) Judgment shall enter in favor of ZOLL and against Philips on Count 2 of ZOLL's Complaint and Counts 2 and 7 of

Philips's Counterclaim to the extent that it is adjudged that Claims 1 and 4 of U.S. Patent No. 5,391,187 are infringed by the Philips HeartStart XL defibrillator and are not invalid but judgment shall enter in favor of Philips and against ZOLL to the extent that it is adjudged that Claims 1 and 4 are not infringed by the Philips HeartStart MRx defibrillator;

10) Philips's claims for judgment of infringement with respect to U.S. Patent Nos. 5,721,482 (Count 2), 5,735,879 (Count 3), 5,773,961 (Count 5), 5,803,927 (Count 7), 6,178,357 (Count 11), 6,304,783 (Count 12), 6,441,582 (Count 14), and 6,871,093 (Count 15) are DISMISSED;

11) ZOLL's counterclaims for a declaratory judgment of non-infringement with respect to U.S. Patent Nos. 5,721,482 (Count 2), 5,735,879 (Count 3), 5,773,961 (Count 5), 5,803,927 (Count 7), 6,178,357 (Count 11), 6,304,783 (Count 12), 6,441,582 (Count 14), and 6,871,093 (Count 15) are DISMISSED;

12) ZOLL's counterclaims for a declaratory judgment of invalidity with respect to U.S. Patent Nos. 5,721,482 (Count 17), 5,735,879 (Count 18), 5,773,961 (Count 20), 5,803,927 (Count 22), 6,178,357 (Count 26), 6,304,783 (Count 27), 6,441,582 (Count 29), and 6,871,093 (Count 30) are DISMISSED;

13) ZOLL's claims for a judgment of infringement of U.S. Patent Nos. 5,470,343 (Count 3), 5,575,807 (Count 4) and RE39,250 (Count 5) are DISMISSED;

14) Philips's counterclaims for a declaratory judgment of non-infringement of U.S. Patent Nos. 5,470,343 (Count 3), 5,575,807 (Count 4) and RE39,250 (Count 5) are DISMISSED; and

15) Philips's counterclaims for a declaratory judgment of invalidity of U.S. Patent Nos. 5,470,343 (Count 3), 5,575,807 (Count 4) and RE39,250 (Count 5) are DISMISSED.

Dated June 20, 2014

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KONINKLIJKE PHILIPS N.V. AND PHILIPS ELECTRONICS NORTH AMERICA CORPORATION,

Plaintiffs/Counterclaim-Defendants,

v.

ZOLL MEDICAL CORPORATION,

Defendant/Counterclaim-Plaintiff.

CIVIL ACTION NO. 10-cv-11041-NMG

PLAINTIFFS' RULE 50(b) MOTION AND MEMORANDUM FOR JUDGMENT AS A MATTER OF LAW AND RULE 59 MOTION AND MEMORANDUM FOR A NEW TRIAL

Motion denied. NMGorton, USDJ 8/13/14

Exhibit-116

1:10-cv-11041-NMG

US005330526A

United States Patent [19]

Fincke et al.

[11] **Patent Number: 5,330,526**

[45] **Date of Patent: Jul. 19, 1994**

[54] COMBINED DEFIBRILLATION AND PACING ELECTRODE

[75] Inventors: Randall W. Fincke, Winchester; Rolf S. Stutz, Cambridge, both of Mass.

[73] Assignee: ZMD Corporation, Wilmington, Del.

[21] Appl. No.: 877,838

[22] Filed: May 1, 1992

[51] Int. Cl.[5] A61B 5/0402
[52] U.S. Cl. 607/142; 607/152
[58] Field of Search 128/639, 640, 798

[56] References Cited

U.S. PATENT DOCUMENTS

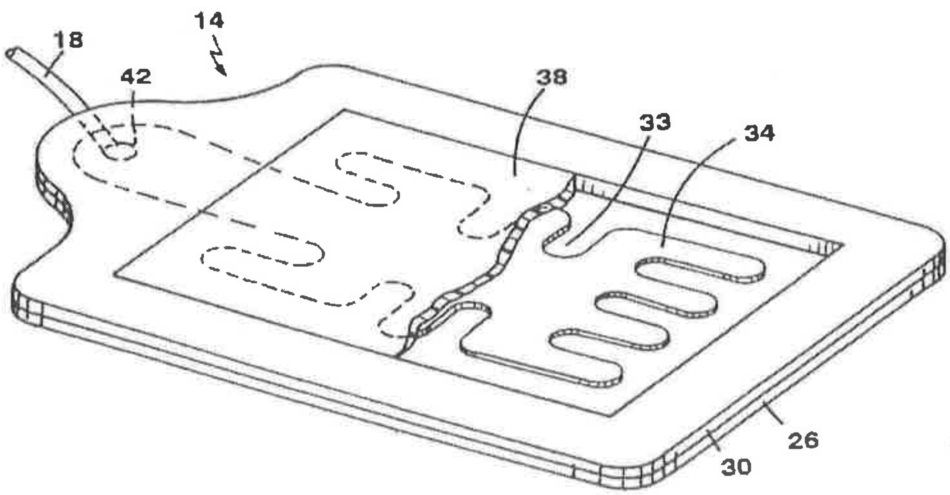
4,391,278	7/1983	Cabalan et al.	128/798
4,538,612	9/1985	Patrick, Jr.	128/639
4,926,878	5/1990	Snedeker	128/798
4,989,607	2/1991	Keusch et al.	128/798

Primary Examiner—William E. Kamm
Assistant Examiner—Scott M. Getzow
Attorney, Agent, or Firm—Fish & Richardson

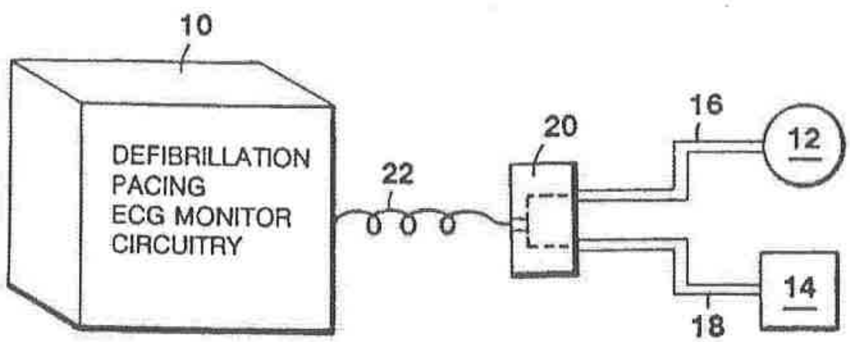
[57] ABSTRACT

An electrode for transcutaneously delivering defibrillation pulses to a patient's heart. The electrode comprises an insulating substrate, a conducting plate which is positioned on the substrate and which has an electrical terminal for making a connection to an external source of electrical current, and a layer of electrolytic gel covering the entire top surface of the conducting plate. This gel contacts a patient's skin when the electrode is positioned on the skin to prevent the conducting plate from contacting the skin. The gel comprises a concentration of an electrolyte such that the combination series resistance of two of the electrodes, when measured with the electrodes configured in a series circuit with a 50 Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, is greater than 1 Ω when a 200 Joule defibrillation pulse is discharged into the series circuit.

42 Claims, 2 Drawing Sheets



PLAINTIFF'S EXHIBIT 116 3-6-13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ECG MONITOR
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FIG. 1

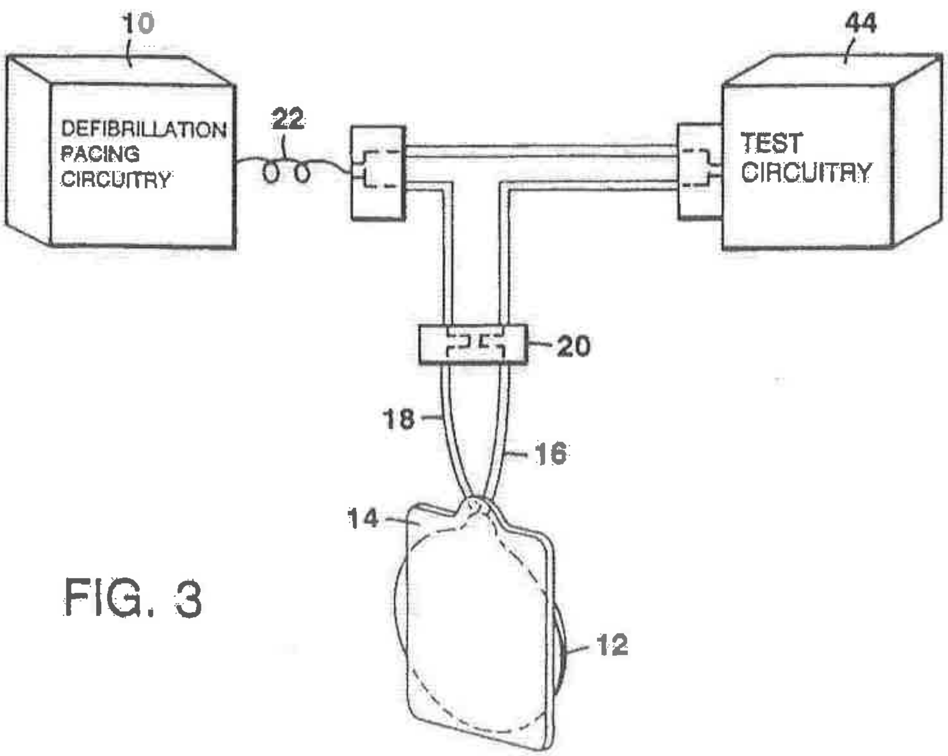
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FIG. 3

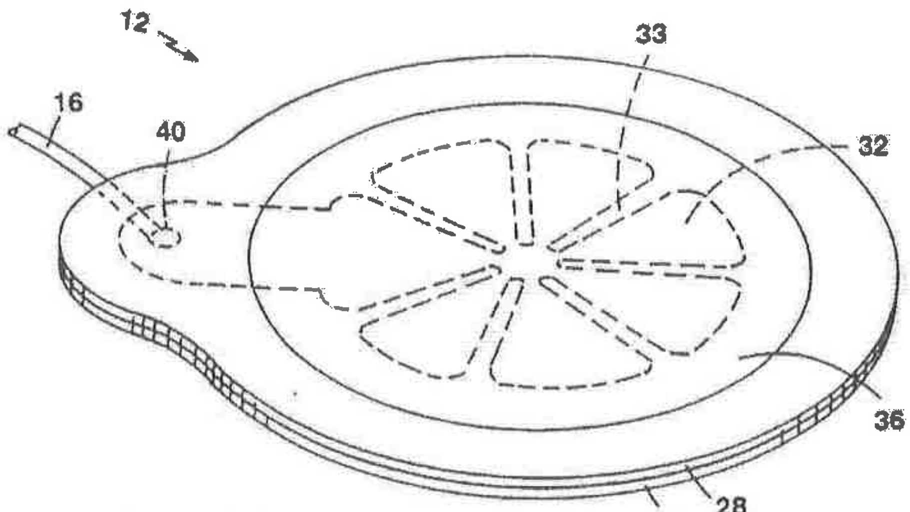

FIG. 2A

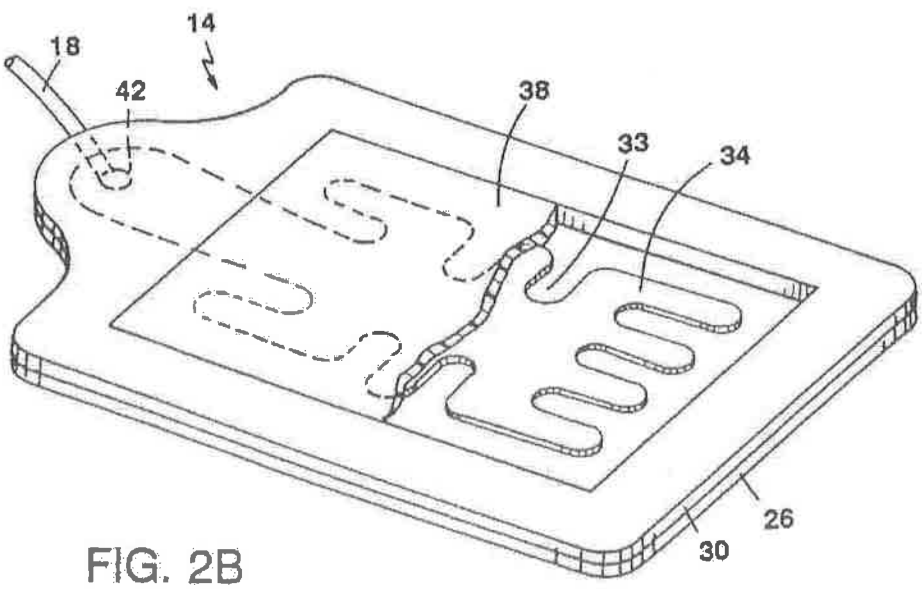

FIG. 2B

COMBINED DEFIBRILLATION AND PACING ELECTRODE

BACKGROUND OF THE INVENTION

This invention relates to electrodes used in transcutaneous cardiac defibrillation and pacing procedures.

Transcutaneous cardiac defibrillation is an emergency procedure for treating ventricular fibrillation, a condition in which the electrical pulse generators in the cardiac muscle fibrillate asynchronously, causing chaotic muscle contraction. In the procedure, a high energy electrical pulse, called a defibrillation pulse, is transcutaneously delivered to a patient's fibrillating heart to resynchronize the heart's pulse generators. In transcutaneous cardiac pacing, pacing stimuli are transcutaneously delivered to a patient's heart to continuously pace the heart.

Defibrillation pulses and pacing stimuli are transcutaneously delivered from pulse generation equipment to a patient via a pair of electrodes applied to the patient's thorax in a suitable configuration. Typically, either of two types of electrodes is used; the first type comprises separate, dedicated defibrillation and pacing electrode pairs, while the second comprises a multifunction electrode pair which supports both defibrillation and pacing procedures.

The multifunction electrode typically consists of a flexible adhesive substrate, supporting a conducting plate, which is temporarily affixed to the patient's skin, and so does not require an operator to forcibly hold it in place on the skin. This electrode is designed to be used for one treatment session and then discarded.

It is desirable to provide a uniform contact surface between the multifunction electrode conducting plate and the patient's skin. To this end, a water-based electrolytic gel is typically provided on the electrode conducting surface. With the electrode in place on the patient's thorax, this gel soaks the skin, allowing the electrolytes in the gel to permeate the skin and thereby provide a good conducting path for the defibrillation and pacing stimuli. In addition, the gel wets hair on the patient's skin and provides a good conductive path around the hair and into the skin. The electrodes are typically gelled during the manufacturing process and require no further preparation before use.

Conventionally, the components of the aqueous electrolytic gel are chosen to achieve very low gel resistance, and thus very high gel conductivity, to minimize the pulse energy dissipated in the gel and thereby maximize the defibrillation pulse energy and pacing stimulus delivered to the patient. The electrical resistance of a patient's thorax is believed to range somewhere between 25 Ω and 100 Ω, and is typically modelled as 50 Ω; the series resistance of the pair of multifunction electrodes, including electrode gel, is held below 1.0 Ω.

In defibrillation procedures, typically more than one defibrillation pulse is required to successfully defibrillate a patient's heart. Being affixed to the patient's skin at the start of a defibrillation session, multifunction electrodes do not change position with each pulse application. It has been clinically observed that with repeated defibrillation pulse applications, some burning of a patient's skin may occur at the perimeter of the gel layer of each of the multifunction electrodes. This burning is characterized by erythema across a thin band at the gel perimeter location. It is believed that the location of the burn is determined by the spatial distribution of the defibrillation pulse current across the electrode and gel face; this current is highest at the perimeter of the gel, due to the abrupt boundary of the electric field at this perimeter. The electrode burn is exacerbated by repeated defibrillation pulses because the multifunction electrodes are maintained in a fixed position throughout a pulse series.

In conventional transcutaneous pacing procedures, the patient may experience a stinging of the skin in the area of the electrodes' positions. This stinging is believed to also be related to the high current level of delivered stimuli at the edge of the conducting plate and gel.

SUMMARY OF THE INVENTION

In general, the invention features increasing the resistance of electrodes used for transcutaneously delivering defibrillation pulses to the heart, and thereby decreasing the potential for burning of the skin during the defibrillation. The electrode comprises an insulating substrate, a conducting plate which is positioned on the substrate and which has an electrical terminal for making a connection to an external source of electrical current, and a layer of electrolytic gel covering the entire surface of the conducting plate. This gel contacts a patient's skin when the electrode is positioned on the skin to prevent the conducting plate from contacting the skin. The gel comprises a concentration of an electrolyte such that the combination series resistance of two of the electrodes, when measured with the electrodes configured in a series circuit with a 50 Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, is greater than 1 Ω when a 200 Joule defibrillation pulse is discharged into the series circuit. The invention provides an electrode gel resistance which is high enough to significantly decrease the potential for burning of a patient's skin at the perimeter location of the electrodes on the skin (by comparison to the burning associated with conventional disposable electrodes); at the same time, the gel resistance is low enough that only an insignificant percentage of the defibrillation pulse is dissipated in the gel resistance.

In preferred embodiments, the combination series resistance of two of the electrodes is at least 1.5 Ω, but not more than 5 Ω. In more preferred embodiments, the combination electrode series resistance is at least 1.5 Ω but not more than 3 Ω.

In preferred embodiments, the electrode is configured to deliver transcutaneous pacing stimuli, in addition to defibrillation pulses. The increased electrode gel resistance decreases the current density of pacing pulses at the perimeter of the electrode, thereby reducing the skin stinging typically associated with conventional transcutaneous pacing electrodes. In addition, the pacing and defibrillation multifunctionality of the electrode provides great efficiency in emergency medical equipment and procedures. Preferably, the electrode comprises a front electrode to be positioned on the front of a patient's chest and a back electrode to be positioned on the back of a patient's chest, and the conducting plates of the front and back electrodes are at least 8 square inches.

In other preferred embodiments, the front and back electrode conducting plates each comprise a geometry which occupies a general region but which spans a geometric area less than that of the general region, and

which has a perimeter which is greater than the perimeter of the region. Preferably, the front and back electrode conducting plates each comprise a geometry including inwardly extending excursions of the perimeter of the geometry at spaced intervals around the geometry perimeter; more preferably, the front electrode conducting plate occupies a generally circular region and the back electrode conducting plate occupies a generally rectangular region. The increased perimeter of the conducting plates' geometries works in concert with the increased resistance of the gel to decrease the current delivered at the perimeter of the plates and thereby decrease the stinging of transcutaneous pacing stimuli.

Other features and advantages of the invention will become apparent from the following description of the preferred embodiment of the invention and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a portable defibrillation and pacing unit connected to the electrodes of the invention.

FIG. 2A is another perspective view of the front electrode shown in FIG. 1.

FIG. 2B is another perspective view of the back electrode shown in FIG. 1.

FIG. 3 is a schematic of a testing circuit for measuring the resistance of the electrodes shown in FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, there is shown a portable defibrillation and pacing unit 10 which includes electrical circuitry needed for generating electrical signals used in emergency defibrillation, pacing, and ECG monitoring procedures. Such a unit is available from Zoll Medical Corporation of Woburn, Mass., under the product name PD1400, as well as other product names. A pair of disposable multifunction electrodes 12, 14 are connected to the defibrillation and pacing unit via corresponding electrode wires 16, 18, which are coupled in a multifunction connector 20 to a cable bundle 22, ending in an electrical connection with the defibrillation and pacing unit.

In operation, the multifunction electrodes 12, 14 are affixed to the front and back of the patient's chest in a position aligned with the patient's heart. As described below, the adhesive property of the electrodes provides for them to remain in position without manual effort. If the patient requires cardiac pacing, the defibrillation and pacing unit is programmed to initiate and maintain appropriate pacing stimuli, which are transcutaneously delivered to the patient's heart. If the patient alternatively or additionally requires cardiac defibrillation, the defibrillation and pacing unit is programmed to discharge a defibrillation pulse, typically having a peak energy in the range of 200–400 Joules. Based on the cardiac response of the patient to the defibrillation pulse, additional defibrillation pulses may be applied to the patient. Throughout the delivery of any cardiac pacing and defibrillation pulses, the electrodes 12, 14 remain intact on the patient's thorax.

Referring to FIGS. 2A and 2B, illustrating the front and back multifunction electrodes 12, 14, respectively, in more detail, the two electrodes are identical except for their lateral shapes. The front electrode 12 is round, for easy placement on the chest area of a patient's thorax, while the back electrode 14 is rectangular, for easy alignment with the spine on the back area of the patient's thorax. An insulating base layer 24, 26 of each electrode is composed of a layer of flexible, closed cell-type polyethylene foam tape. The flexibility of the tape allows it to conform to the contours of a patient's thorax when the electrodes are affixed to the thorax. While other types of base layer materials are acceptable, the base material must be of a high enough density to provide a liquid barrier to aqueous gel so as to hold the gel on one side of the electrode, as described below, and must have excellent compressibility qualities.

The dimensions of the foam base layer are determined based on physiological considerations for both transcutaneous pacing and defibrillation. The area of the electrodes' conducting plates, which are smaller than the corresponding base layers, must be larger than that of the heart; cardiac defibrillation is not effective unless the entire heart is in effect "covered" by a defibrillation pulse. Other considerations for pacing and defibrillation are described below. In addition, the base layer dimensions are here chosen to provide some amount of area surrounding the conducting plates for adhesion to a patient's thorax. The Association for the Advancement of Medical Instrumentation (AAMI) specifies that the smallest adult defibrillation conducting plate may be 8 square inches. Thus, any area at least this large would be acceptable in theory for the insulating base layer. Here the front electrode 12 has a round foam base of 6 inches in diameter, with a corresponding area of 28.3 in^2. The back electrode 14 has a rectangular foam base of 5 inches by 6.5 inches, with a corresponding area of 32.5 square inches. As explained below, these dimensions provide adequate mechanical support for the electrode conducting plates and space for adhesive support.

The thickness of the base layers is also determined based on physiological factors. A thin base layer easily conforms to the contours of a patient's thorax, while a thick base layer evenly supports the metal electrode and provides more even current distribution across the electrode. A trade-off must be made between these two opposing considerations. Here, the foam base layer of each of the electrodes is ⅛ inch-thick; other thicknesses may be used based on particular situations.

Supported by the foam base layers 24, 26 are peripheral foam frames 28, 30, respectively, which border conducting plates 32, 34, sandwiched between the foam base layers 24, 26 and upper gel-filled layers 36, 38, respectively. The frames provide mechanical support at the periphery of the electrode assembly and define an inner well in which the conducting plates and gel-filled layers are positioned. The front electrode foam frame 28 is 1 inch-wide, defining an inner well of 12.3 square inches; the back electrode foam frame 30 is 0.8 inches-wide, defining an inner well of 17.5 square inches. Each of the foam frames 28, 30 comprise the same polyethylene foam tape as the base layers. These foam frames are 1/16 inch-thick; other thicknesses may be used based on particular situations. The foam frames are affixed to the bottom foam layers with hot melt all-purpose glue.

The top surface of each of the foam frames is coated with a hypoallergenic medical grade acrylic adhesive designed for use on human skin. This adhesive provides the mechanism for temporarily affixing the electrodes in position on a patient's thorax. Using this adhesive, no additional adhesive or any manual force is required to maintain the electrodes in position during delivery of electrical signals to a patient.

The electrode conducting plates 32, 34 located in the wells defined by the foam frames, are of a geometry selected for promoting even distribution of electrical current across the area of the electrodes. Here, the front electrode conducting plate 32 is generally circular (occupies a generally circular region) but includes inwardly extending excursions 33 of the perimeter. Likewise, the back electrode conducting plate 34 is generally rectangular and also includes inwardly extending excursions 33 of the perimeter. These inward excursions are about one third as long as the diameter of the electrode (or in the case of the rectangular electrode, one third the transverse dimension). Less of an inward excursion may be used; preferably the excursion is at least one fifth of the transverse dimension of the conducting plate. This type of geometry is chosen to increase the conducting plate perimeter beyond that which would be obtained using a continuous geometry. The increased perimeter of the conducting plate works in concert with the increased gel resistance to decrease the stinging of skin typically associated with transcutaneous pacing; the longer the perimeter for a given conducting plate geometry, and the higher the resistance of the gel, the more comfortable the pacing stimuli are to a patient. In addition to this geometric feature, neither of the conducting plate geometries includes a point or corner. This eliminates discontinuities, at which a high electric field, and correspondingly high current density, could be generated. Each of the conducting plates terminates ¼ inch from the edge of the foam frame border, and therefore is ¼ inch smaller than the layer covering it, as described below. Other conducting plate geometries, including a continuous geometry, may alternatively be used.

As mentioned previously, the dimensions of the conducting plates must meet a requirement for being large enough to defibrillate the heart. A larger size conducting plate, as opposed to a smaller conducting plate, is also desirable because for a given defibrillation current pulse, the larger plate decreases the current amplitude at the edge of the plate (compared to a smaller plate), and thereby decreases the potential for burning associated with that current amplitude. In addition, the larger the electrode conducting plate, the more likely are pacing stimuli are to capture, and thereby pace, some of the cardiac pacing cells. Conversely, the smaller the electrode conducting plate, the more effective it is at pacing cardiac pacing cells it does capture, because the pacing current is increased in a smaller area, which more effectively stimulates the pacing cells. Based on all of these considerations, the front electrode conducting plate 32 here spans an area of 8.4 square inches and the back electrode conducting plate 34 spans an area of 11.7 square inches, both conducting plate areas being in conformance with the AAMI minimum conducting plate area requirement of 8 square inches, and optimizing the size for cardiac pacing procedures.

Both conducting plates are composed of a 0.001 inch-thick layer of tin laminated to a 0.006 inch-thick layer of Tyvek. Having a total thickness of 0.007 inches, the electrodes are radio-translucent. Thus an x-ray taken of the thorax region of a patient with the electrodes affixed to his thorax will be only minimally shadowed by the presence of the electrodes. This is particularly important because frequently a patient having recurring cardiac distress will require cardiac pacing or defibrillation during a session to take an x-ray. If such a provision for radio-translucency is not required, the conducting plate may be of some higher thickness, and may also comprise some other good conducting material. For example, a thicker conducting plate would provide good mechanical qualities, but would not be as radio-translucent as a thinner electrode.

Each conducting plate 32, 34 includes an extension area 40, 42, respectively, which extends laterally beyond the layer covering the plate but which is itself covered by the foam frame border 28, 30, respectively. Each foam border is correspondingly extended in the location of the conducting plates' extension areas. It is at the extension areas 40, 42 that the conducting plates are electrically connected to corresponding electrical wires 16, 18 for connection back to the portable pacing and defibrillation unit. This connection is here made using a rivet technique, but other techniques are also feasible. The electrical wires 16, 18 are 20 gauge and rated for 10 KV to adequately support high energy defibrillation pulses. They comprise copper wire insulated with a PVC coating.

Each conducting plate 32, 34 is positioned tin side up within the foam well. It is completely covered by a corresponding reticulated open cell-type gel foam layer 36, 38 designed to support an amount of aqueous electrolytic gel. The front electrode gel foam layer 36 is circular, having a diameter of 3.95 inches and an area of 12.3 square inches. The back electrode gel foam layer 38 is rectangular, having sides 3.5 inches by 5 inches and an area of 17.5 square inches. Thus, gel foam layers 36, 38 fit exactly within the windows defined by the outer foam borders 28, 30.

The gel foam layers 36, 38, like the conducting plates 32, 34 under them, may comprise a geometry which maximizes the gel perimeter for a given general shape. For example, the front electrode gel foam layer 36 may include excursions 33 to thereby increase the layer perimeter beyond that which a simple circle would provide. This design could be used with the front conducting plate 32 having excursions 33 as shown, or with a simple circular plate. An increased gel layer perimeter decreases the level of current delivered to the patient at the perimeter; this decreased current correspondingly decreases the potential for burning associated with the electrode during defibrillation.

Each gel foam layer 36, 38 is 3/16 inch-thick. Because the wells defined by outer foam borders 28, 30 are ⅛ inch-thick, the gel foam layers 36, 38 protrude above the foam borders 28, 30 by 1/16 inch. This additional gel foam thickness ensures that very good contact is made to a patient's skin when the electrodes are affixed to the skin. With the stated areas and thickness, the front gel foam layer 36 has a gel space capacity of 37.5 cm^3 and the back gel foam layer 38 has a gel space capacity of 32.5 cm^3.

The gel which is supported by the gel foam layers 36, 38 is a viscous, clear, aqueous electrolytic gel composed of a polymer, a surface active agent, a corrosion inhibitor, a salt, here sodium chloride, preservatives, and purified water. It has a pH between 5 and 6. The front electrode's gel foam layer 36 is filled with 33 grams of the gel, which fills the layer to 88% of its capacity. The back electrode's gel foam layer 38 is filled with 47 grams of the gel, which fills the layer to 87% of its capacity. The gel-soaked foam layers 36, 38 completely wet and cover the underlying metal conducting plates; this is important for avoiding direct contact of the plates to a patient's skin when the electrodes are in position on a patient, a situation which could cause discomfort. The

electrodes' foam base layers 24, 26, being quite dense, prevent the gel from penetrating under the conducting plates and through the base to the outer back side of the base layers, and thereby prevent any accidental electrical shock to a medical operator.

The sodium chloride (NaCl) concentration of the gel determines the electrical resistance of the gel. The lower the NaCl concentration, the higher the resistance of the gel. This resistance dissipates some of the energy in the electrical pulse signals delivered to the electrodes from the signal generation equipment, and thereby decreases the pulse energy ultimately delivered to a patient. The AAMI specifies that the defibrillation pulse energy delivered to a 50 Ω resistive load, the typical resistance of a patient's thorax, must be within 4 Joules or +/- 15%, whichever is greater, of the pulse energy generated by the electrical signal generation equipment. Thus, for a defibrillation pulse energy specified to be 200 Joules, the pulse energy reaching a patient through the electrodes must be between 170 and 230 Joules. The AAMI also specifies that the peak current of a 360 Joule defibrillation pulse delivered to a 50 Ω resistive load must be between 45 and 66 Amps.

Fundamentally, and in addition to these considerations, the electrolyte concentration, and correspondingly the resistance, of the gel is chosen based on a desire to eliminate the potential for burning of a patient's skin at the perimeter of the electrodes during defibrillation, and to decrease the discomfort typically associated with transcutaneous pacing. The burning is caused by the nonuniform distribution of current across the conducting plates; the current is highest at the perimeter of a conducting plate, due to the abrupt boundary of the electric field at this perimeter. Thus, a reduction in the defibrillation current density at the plate and gel edge results in a decrease in the potential for burning of a patient's skin. Similarly, a decrease in the level of pacing stimuli at the plate perimeter makes transcutaneous pacing more comfortable for a patient. While NaCl is the electrolyte used here, other salts may alternatively be used which would exhibit similar conductivity and impedance characteristics.

The gel's NaCl concentration and corresponding gel resistance is here chosen to be somewhere in the range which meets the AAMI defibrillation standards requirements and which provides the physiological benefits described above. To accurately determine the gel resistance as a function of NaCl concentration, the gelled electrodes are tested in the test setup illustrated in *FIG.* 3. In this configuration, the front electrode **12** is adhered to the back electrode **14**, with the gel foam layers **36**, **38** of the two electrodes facing and in contact with each other. The connecting wires **16**, **18** of the two electrodes are connected via the multifunction connector 20 to the defibrillation and pacing unit 10 and a test circuit unit 44, for example, a Dynatech Impulse 3000 tester. A series loop is thus configured to consist of the defibrillation and pacing unit 10, the front electrode 12, the back electrode **14**, and the test circuit unit **44**. The test circuit unit 44 is configured to provide a resistive load, for example, 50 Ω resistor, simulating the resistive load of a patient's thorax, and corresponding measurement circuitry.

With a 200 Joule defibrillation pulse generated by the defibrillation circuit and the test circuit 44 configured to provide a 50 Ω resistive load, the following NaCl concentrations, specified in percent weight per volume, are shown to produce the corresponding resistance of the combination of the two electrodes in series, and the corresponding energy delivered to the load—a short circuit in place of the electrodes is used as the control:

NaCl CONC.	ELECTRODE RESISTANCE	ENERGY DELIVERED
4.7%	0.88 Ω	204.59 Joules
1.5%	1.55 Ω	202.58 Joules
1.0%	2.30 Ω	200.21 Joules
Short	0–0.005 Ω	207.50 Joules

In clinical tests of electrodes using gels of the 4.7%, 1.5%, and 1.0% NaCl concentrations, it is found that the physiological electrode edge burn of electrodes using either of the 1.5% and 1.0% NaCl concentration gels is dramatically reduced from that of the 4.7% NaCl concentration gel. In these two cases, skin at the perimeter of the electrodes is reddened after a defibrillation pulse application, but this redness is not as pronounced as that caused by the electrodes with the 4.7% NaCl, and more pulses must be applied before the skin is actually burned. Thus, the lower NaCl concentrations clearly aid in reducing burning caused by the electrodes. In addition, transcutaneous pacing using the lower NaCl-concentration gels is more comfortable, compared to a higher NaCl-concentration gel. An additional benefit of a reduced NaCl concentration in the electrode gel is a decrease in the corrosive tendencies of the conducting plate-gel configuration.

Considering the AAMI requirement for delivering within +/-15% of the energy of a generated defibrillation pulse to a 50 Ω load, all of the NaCl gels (4.7%, 1.5%, and 1.0%) meet this requirement; in fact, using the short circuit load test as a baseline, the three electrodes deliver at least 96.5% of the 200 Joule pulse to a 50 Ω load, for a maximum energy loss of only 3.5%. Based on these results, the 1.55 Ω electrode is preferred, but an acceptable range of possible resistances exists; the lower bound on resistance is set by the electrode burning phenomenon, and the upper bound is set by the loss of pulse energy into the resistive gel.

The final components of the electrodes are plastic covers (not shown) for protecting the electrode assemblies during storage. The covers comprise 10 mil-thick sheets of natural styrene coated with a layer of thermal cured silicone; this layer faces the gel foam when correctly positioned. The shape and size of each cover is identical to the foam base layer of the corresponding electrode. The covers are contoured to accommodate the 1/16 inch protrusion of the gel foam layer above the rest of the electrode surface.

In assembly of the multifunction electrode pair, the gel foam layers are first positioned within their corresponding foam frames, and the conducting plates are riveted to corresponding connection wires and positioned under the gel foam layers, with the tin side of the plates facing toward the gel foam layers. Then the foam border layers, with the gel foam layers and conducting plates in position, are glued to the corresponding foam base layer. Next the polymer gel is applied to the gel foam layers in the prescribed quantities. Finally, the styrene plastic covers are affixed on the gel foam side of the electrode assembly.

Other embodiments are within the scope of the invention. For example, the foam base and border pieces may together be an integral structure, rather than two sepa-

rate pieces. The gel foam layer may comprise some other material or mechanism for supporting an electrolytic gel, or may provide for the application of gel before electrode use, rather than at the time of manufacture. Other electrolytic gels may be used in place of that described, and may be solid, rather than aqueous.

What is claimed is:

1. An electrode for transcutaneously delivering defibrillation pulses to a patient's heart, the electrode comprising:

an insulating substrate,

a conducting plate having a top surface, a bottom surface, and an electrical terminal for making a connection to an external source of electrical current, said conducting plate being positioned with said bottom surface on said substrate, and

a layer of electrolytic gel comprising a concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a 50 Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than 1 Ω when a 200 Joule defibrillation pulse is discharged into the series circuit, said layer of electrolytic gel covering the entire top surface of said conducting plate, the gel contacting a patient's skin when the electrode is positioned on the patient's skin to thereby prevent said conducting plate from contacting the patient's skin.

2. The electrode of claim 1 wherein said combination series resistance is at least 1.5 Ω.

3. The electrode of claim 2 wherein said combination series resistance is not more than 5 Ω.

4. The electrode of claim 3 wherein said combination series resistance is not more than 3 Ω.

5. The electrode of claim 1 wherein said combination series resistance is at least 5 Ω.

6. The electrode of claim 1 wherein said combination series resistance is such that the energy of said defibrillation pulse discharged into said series circuit delivered to said 50 Ωresistance is within 30 Joules of the 200 Joule defibrillation pulse.

7. The electrode of claim 6 wherein said combination series resistance is such that the energy of said defibrillation pulse discharged into said series circuit delivered to said 50 Ω resistor is within 20 Joules of the 200 Joule defibrillation pulse.

8. The electrode of claim 1 wherein said electrode conducting plate occupies a general region having an area that is greater than the surface area of the electrode conducting plate and a perimeter that is less than the perimeter of the electrode conducting plate.

9. The electrode of claim 8 wherein said electrode is intended to be disposed of after use.

10. The electrode of claim 9 further comprising a removable insulating cover which when positioned on the electrode entirely covers the electrolytic gel layer, the cover designed to be removed from the electrode prior to use of the electrode.

11. The electrode of claim 1 wherein said electrolyte is a salt.

12. The electrode of claim 11 wherein said salt is sodium chloride.

13. The electrode of claim 12 wherein said layer of electrolytic gel is supported by a layer of foam covering the entire top surface of said conducting plate so that said foam contacts said patient's skin when the electrode is positioned on the skin, the foam being soaked with said electrolytic gel.

14. The electrode of claim 13 wherein said foam layer is at least 3/16 inch-thick.

15. The electrode of claims 1 or 14 wherein a portion of the substrate extending beyond the area of the conducting plate includes adhesive for temporarily affixing the electrode to a patient's skin.

16. The electrode of claim 15 wherein said adhesive comprises a medical grade acrylic adhesive.

17. The electrode of claim 15 wherein the area of the substrate extending beyond the area of the conducting plate comprises a boarder layer of flexible foam positioned on top of said substrate and encircling said conducting plate.

18. The electrode of claim 17 wherein the top surface of said border layer is coated with said adhesive for temporarily affixing the electrode to a patient's skin.

19. The electrode of claim 1 wherein said substrate has an area larger than the area of the conducting plate.

20. The electrode of claim 19 wherein said insulating substrate comprises a layer of flexible foam at least 1.8 inches-thick.

21. The electrode of claim 1 wherein the conductivity of said electrolytic gel is less than or equal to the conductivity of a gel comprising a sodium chloride concentration of 4.7% weight per volume of the gel.

22. The electrode of claim 21 wherein the conductivity of said electrolytic gel is less than or equal to the conductivity of a gel comprising a sodium chloride concentration of 1.5% weight per volume of the gel.

23. The electrode of claim 22 wherein said electrolytic gel is a water-based polymer gel.

24. A set of electrodes, each of said electrodes comprising:

an insulating substrate,

a conducting plate having a top surface, a bottom surface, and an electrical terminal for making a connection to an external source of electrical current, said conducting plate being positioned with said bottom surface on said substrate, and

a layer of electrolytic gel comprising a concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a 50 Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than 1 Ω when a 200 Joule defibrillation pulse is discharged into the series circuit, said layer of electrolytic gel covering the entire top surface of said conducting plate, the gel contacting said patient's skin when the electrode is positioned on the patient's skin to thereby prevent said conducting plate from contacting the skin,

said set of electrodes comprising a front electrode to be positioned on the front of a patient's chest and a back electrode to be positioned on the back of a patient's chest, the conducting plate of the front electrode having an area of at least 8 square inches and the conducting plate of the back electrode having an area of at least 8 square inches.

25. The set of electrodes of claim 24 wherein the shape of the perimeter of each of said electrode conducting plates is such that each said electrode conducting plate occupies a general region having an area that is greater than the surface area of the electrode conduct-

ing plate and a perimeter that is less than the perimeter of the electrode conducting plate.

26. The electrode of claim 25 wherein said front set of electrodes conducting plate occupies a generally circular region and said back electrode conducting plate occupies a generally rectangular region.

27. The electrode of claim 24 wherein said front set of electrodes conducting plate and said back electrode conducting plate each comprises a continuous geometry including inwardly extending excursions of the perimeter of said geometry at spaced intervals around the perimeter of said geometry.

28. The set of electrodes of claim 27 wherein each of said inward perimeter excursions extends into said geometry a distance of at least one fifth of the transverse dimension of said plate in the direction of said excursion.

29. The set of electrodes of claim 24 wherein said layer of gel of the front electrode has an area of at least 8 square inches and said layer of gel of the back electrode has an area of at least 8 square inches.

30. The set of electrodes of claim 29 wherein each of said layers of gel occupies a general region having an area that is greater than the surface area of the layer of gel and a perimeter that is less than the perimeter of the layer of gel.

31. The set of electrodes of claim 30 wherein said insulating substrate of said front electrode and said insulating substrate of said back electrode each has an area of at least 8 square inches.

32. A method of transcutaneously defibrillating a patient's heart, the method comprising the steps of:

generating an electrical defibrillation pulse, and

delivering said pulse to said patient through electrodes applied to said patient's thorax, the electrodes each comprising:

an insulating substrate,

a conducting plate having a top surface, a bottom surface, and an electrical terminal for making a connection to receive said electrical defibrillation pulse, said conducting plate being positioned with said bottom surface on said substrate, and

a layer of electrolytic gel comprising a concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a 50 Ω resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than 1 Ω when a 200 Joule defibrillation pulse is discharged into the series circuit, said layer of electrolytic gel covering the entire top surface of said conducting plate, the gel contacting a patient's skin when the electrode is positioned on the patient's skin to thereby prevent said conducting plate from contacting the patient's skin.

33. The method of claim 32 further comprising the steps of:

generating electrical pacing stimuli, and

transcutaneously delivering said electrical pacing stimuli to said patient's heart through said electrodes applied to said patient's thorax.

34. The method of claim 32 wherein said defibrillation pulse has an energy between 200 and 400 Joules.

35. The method of claim 32 wherein the difference between the energy of said defibrillation pulse delivered to said patient and the total energy of said defibrillation pulse is less than or equal to the larger of 10% of the total energy of said defibrillation pulse or 4 Joules.

36. The method of claim 35 wherein said difference is less than or equal to 10% of the total energy of said defibrillation pulse.

37. The method of claim 32 wherein said combination series resistance is at least 1.5 Ω.

38. The method of claim 37 wherein said combination series resistance is at least 5 Ω.

39. The method of claim 37 wherein said combination series resistance is not more than 5 Ω.

40. The method of claim 39 wherein said combination series resistance is not more than 3 Ω.

41. The method of claim 32 wherein the energy of said defibrillation pulse discharged into said series circuit delivered to said 50 Ω resistor is within 30 Joules of the 200 Joule defibrillation pulse.

42. The method of claim 41 wherein the energy of said defibrillation pulse discharged into said series circuit delivered to said 50 Ω resistor is within 20 Joules of the 200 Joule defibrillation pulse.

* * * * *

Exhibit-1
1:10-cv-11041-NMG

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United States Patent [19]

Cameron et al.

[11] **Patent Number: 5,607,454**

[45] **Date of Patent: Mar. 4, 1997**

[54] **ELECTROTHERAPY METHOD AND APPARATUS**

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[21] Appl. No.: **227,553**

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[51] **Int. Cl.**[6] **A61N 1/39**

[52] **U.S. Cl.** **607/5**; 607/7; 607/6; 607/74; 607/62

[58] **Field of Search** 607/2, 4, 5–7, 607/62, 74

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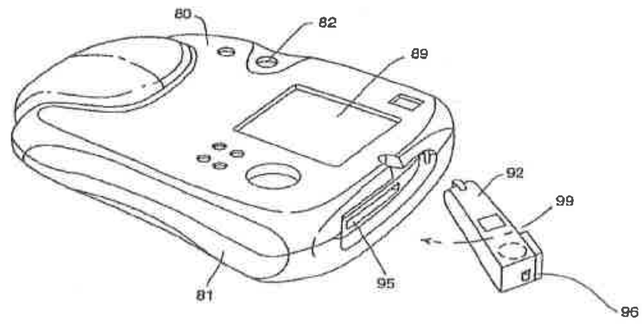
[57] **ABSTRACT**

An electrotherapy method and apparatus for delivering a multiphasic waveform from an energy source to a patient. The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform; monitoring a patient-dependent electrical parameter during the discharging step; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter. The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu. in.

59 Claims, 4 Drawing Sheets



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Product information for MSA Portable Defibrillator (Bulletin No. 1108–1); 4 pp.

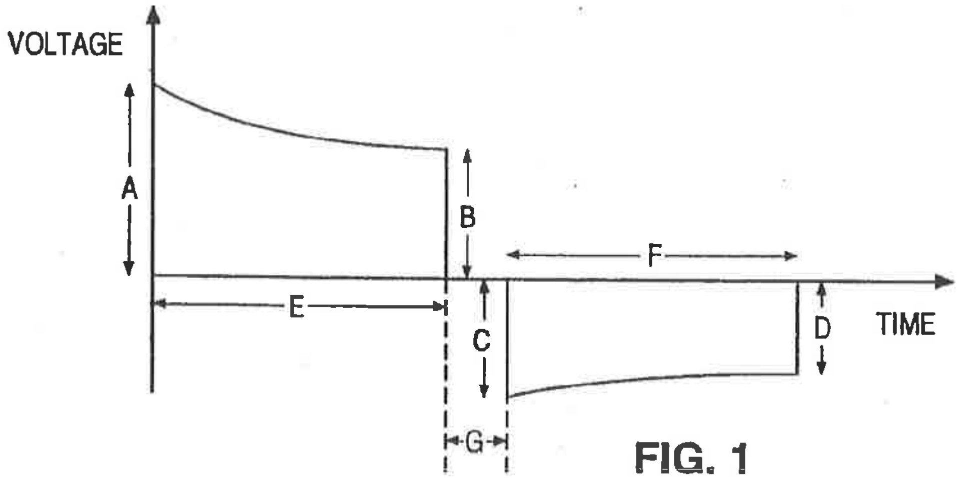

FIG. 1

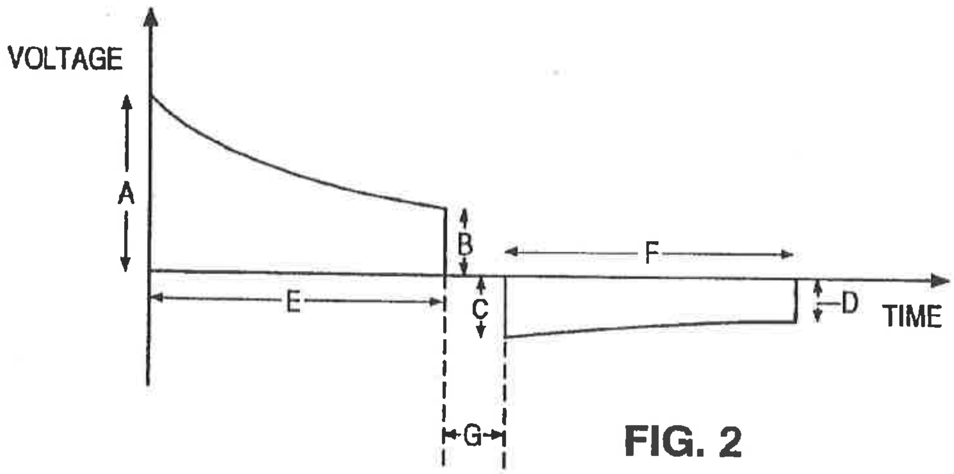

FIG. 2

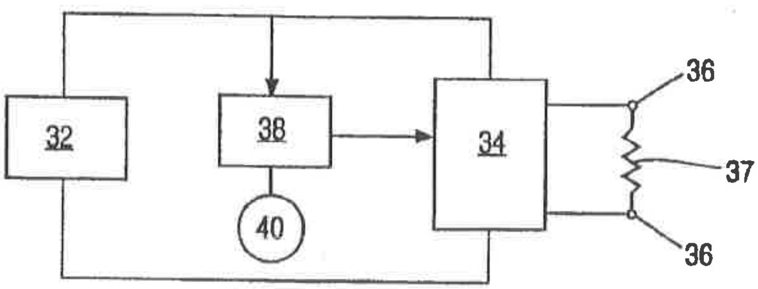

FIG. 3

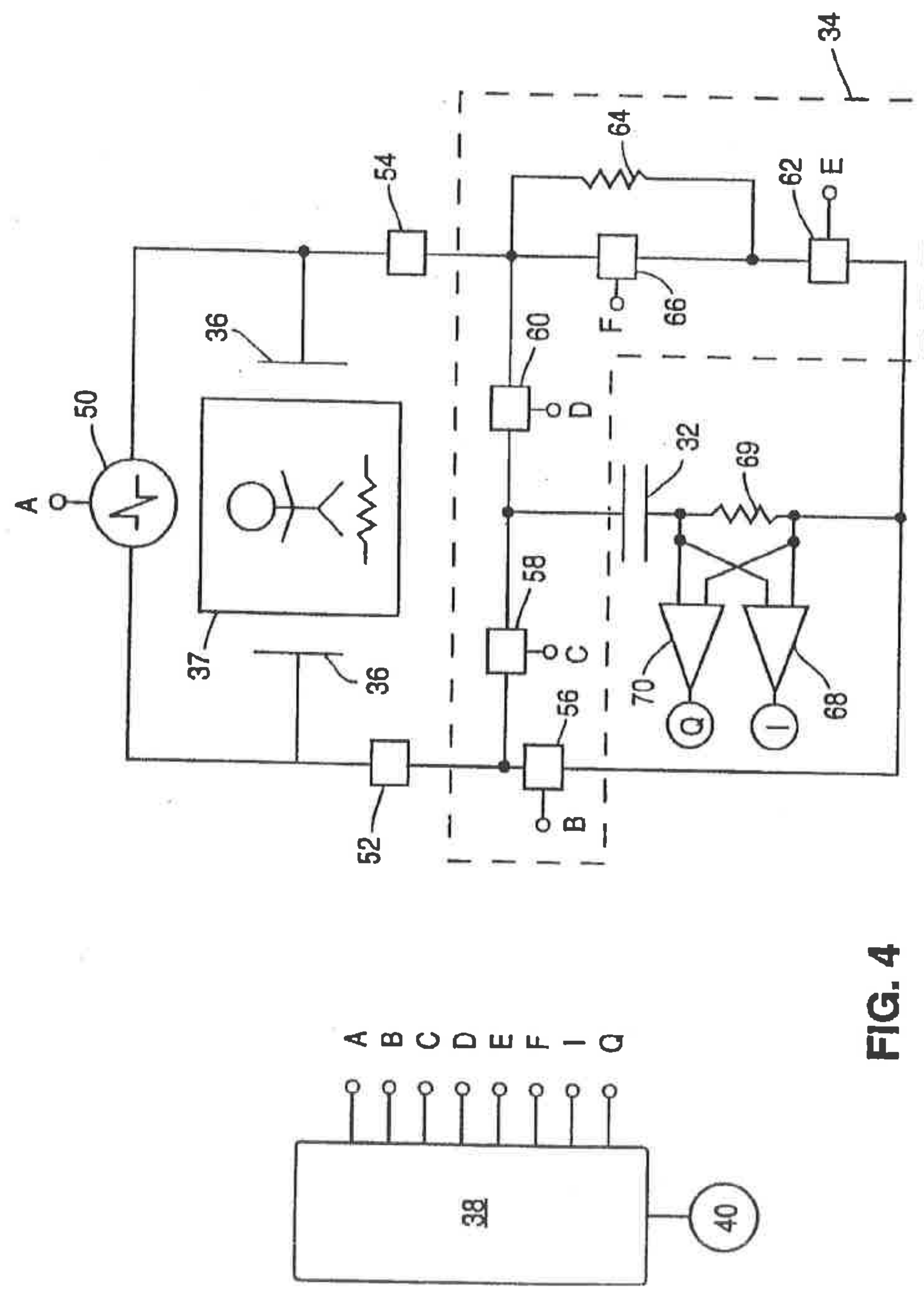
34
64
54
62
E
36
60
F
66
50
A
D
32
69
37
58
C
36
70
68
56
Q
I
52
B
A B C D E F I Q
38
40

FIG. 4

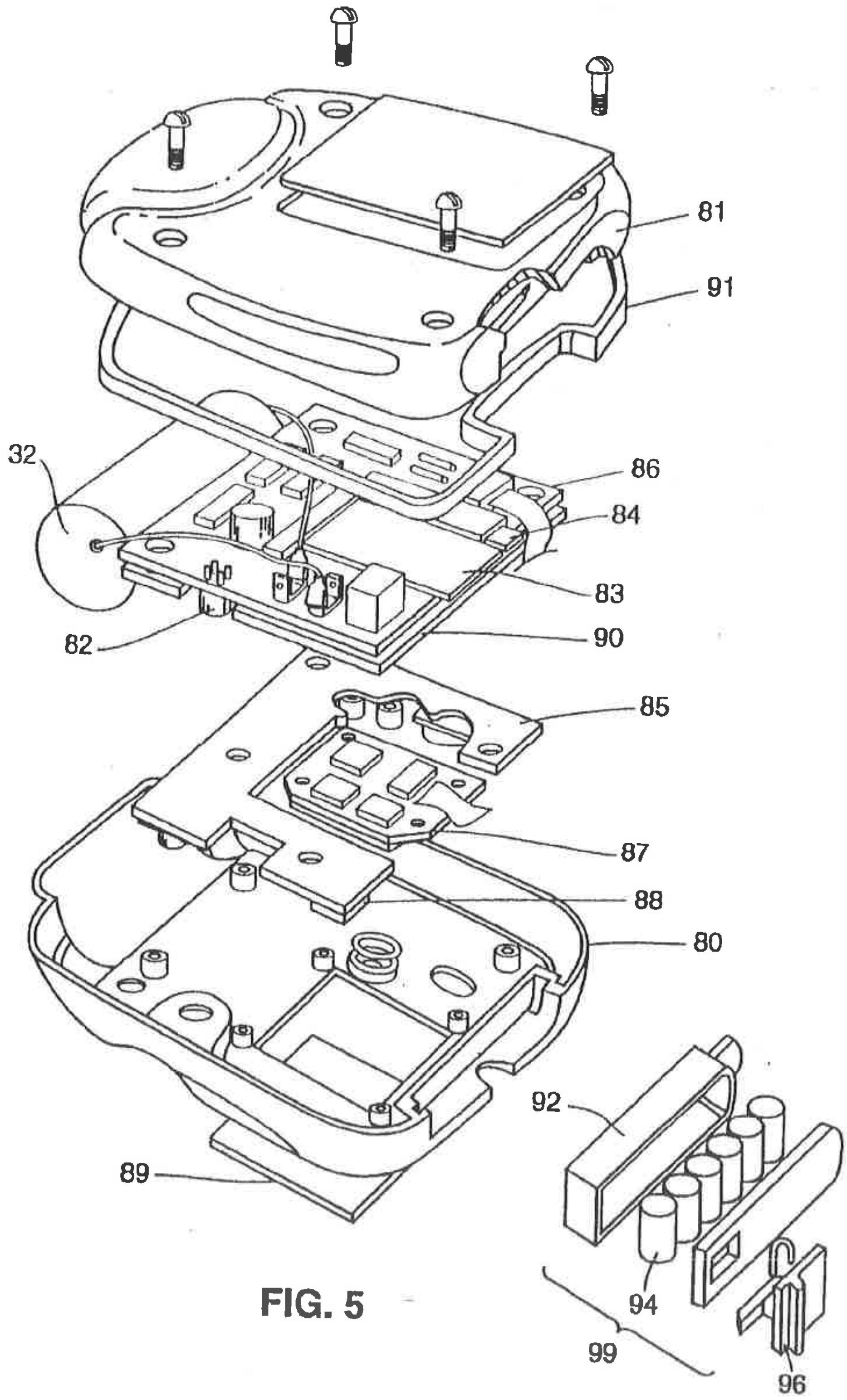

FIG. 5

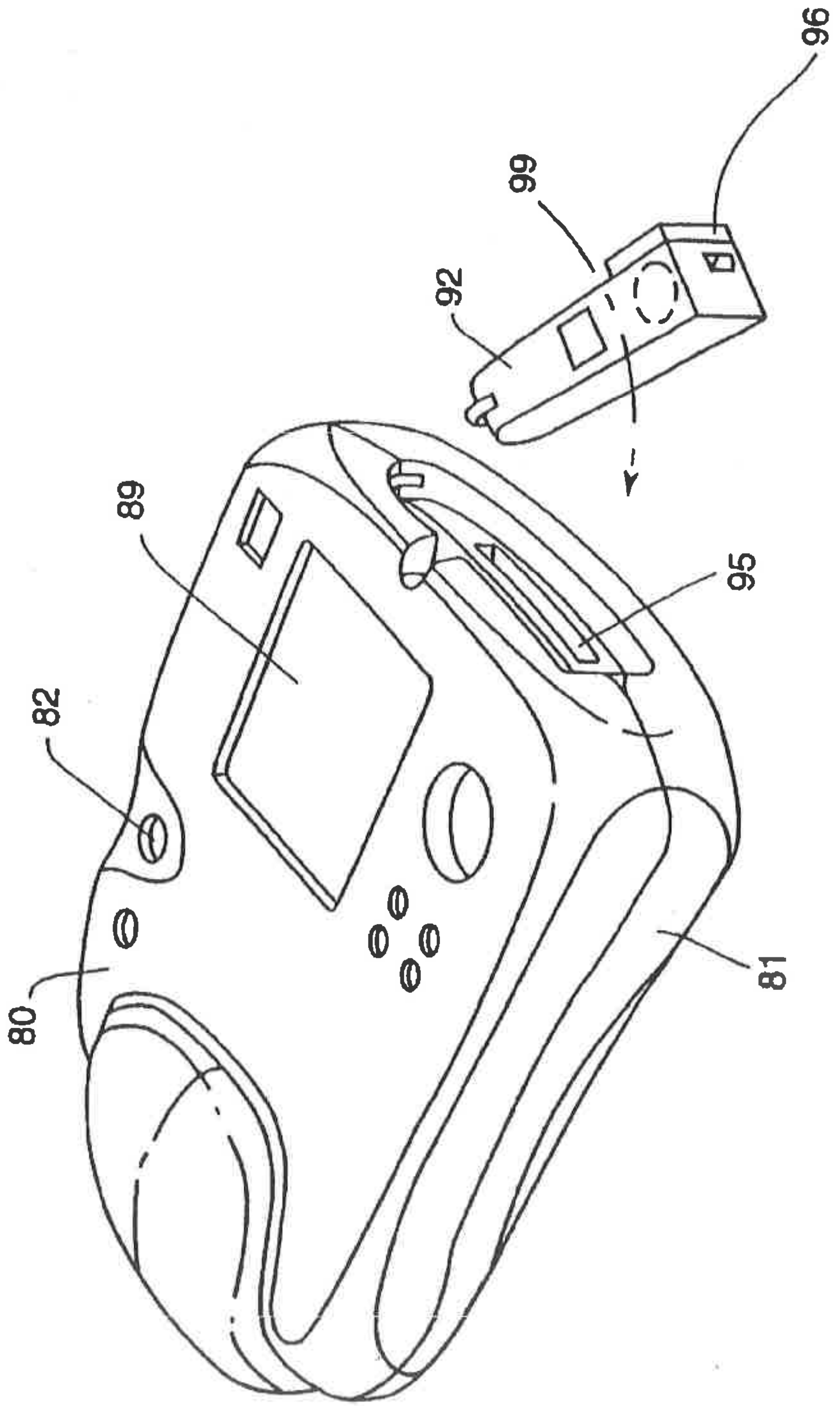

FIG. 6

ELECTROTHERAPY METHOD AND APPARATUS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 08/103,837 filed Aug. 6, 1993, the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to an electrotherapy method and apparatus for delivering an electrical pulse to a patient's heart. In particular, this invention relates to a method and apparatus for shaping the electrical waveform delivered by the defibrillator based on an electrical parameter measured during delivery of the waveform. The invention also relates to a defibrillator design meeting certain threshold size and weight requirements.

Sudden cardiac death is the leading cause of death in the United States. Most sudden cardiac death is caused by ventricular fibrillation, in which the heart's muscle fibers contract without coordination, thereby interrupting normal blood flow to the body. The only effective treatment for ventricular fibrillation is electrical defibrillation, which applies an electrical shock to the patient's heart.

To be effective, the defibrillation shock must be delivered to the patient within minutes of the onset of ventricular fibrillation. Studies have shown that defibrillation shocks delivered within one minute after ventricular fibrillation begins achieve up to 100% survival rate. The survival rate falls to approximately 30% if 6 minutes elapse before the shock is administered. Beyond 12 minutes, the survival rate approaches zero.

One way of delivering rapid defibrillation shocks is through the use of implantable defibrillators. Implantable defibrillators are surgically implanted in patients who have a high likelihood of needing electrotherapy in the future. Implanted defibrillators typically monitor the patient's heart activity and automatically supply electrotherapeutic pulses directly to the patient's heart when indicated. Thus, implanted defibrillators permit the patient to function in a somewhat normal fashion away from the watchful eye of medical personnel. Implantable defibrillators are expensive, however, and are used on only a small fraction of the total population at risk for sudden cardiac death.

External defibrillators send electrical pulses to the patient's heart through electrodes applied to the patient's torso. External defibrillators are useful in the emergency room, the operating room, emergency medical vehicles or other situations where there may be an unanticipated need to provide electrotherapy to a patient on short notice. The advantage of external defibrillators is that they may be used on a patient as needed, then subsequently moved to be used with another patient.

However, because external defibrillators deliver their electrotherapeutic pulses to the patient's heart indirectly (i.e., from the surface of the patient's skin rather than directly to the heart), they must operate at higher energies, voltages and/or currents than implanted defibrillators. These high energy, voltage and current requirements have made existing external defibrillators large, heavy and expensive, particularly due to the large size of the capacitors or other energy storage media required by these prior art devices. The size and weight of prior art external defibrillators have limited their utility for rapid response by emergency medical response teams.

Defibrillator waveforms, i.e., time plots of the delivered current or voltage pulses, are characterized according to the shape, polarity, duration and number of pulse phases. Most current external defibrillators deliver monophasic current or voltage electrotherapeutic pulses, although some deliver biphasic sinusoidal pulses. Some prior art implantable defibrillators, on the other hand, use truncated exponential, biphasic waveforms. Examples of biphasic implantable defibrillators may be found in U.S. Pat. No. 4,821,723 to Baker, Jr., et al.; U.S. Pat. No. 5,083,562 to de Coriolis et al.; U.S. Pat. No. 4,800,883 to Winstrom; U.S. Pat. No. 4,850,357 to Bach, Jr.; U.S. Pat. No. 4,953,551 to Mehra et al.; and U.S. Pat. No. 5,230,336 to Fain et al.

Because each implanted defibrillator is dedicated to a single patient, its operating parameters, such as electrical pulse amplitudes and total energy delivered, may be effectively titrated to the physiology of the patient to optimize the defibrillator's effectiveness. Thus, for example, the initial voltage, first phase duration and total pulse duration may be set when the device is implanted to deliver the desired amount of energy or to achieve a desired start and end voltage differential (i.e., a constant tilt). Even when an implanted defibrillator has the ability to change its operating parameters to compensate for changes in the impedance of the defibrillators leads and/or the patient's heart (as discussed in the Fain patent), the range of potential impedance changes for a single implantation in a single patient is relatively small.

In contrast, because external defibrillator electrodes are not in direct contact with the patient's heart, and because external defibrillators must be able to be used on a variety of patients having a variety of physiological differences, external defibrillators must operate according to pulse amplitude and duration parameters that will be effective in most patients, no matter what the patient's physiology. For example, the impedance presented by the tissue between external defibrillator electrodes and the patient's heart varies from patient to patient, thereby varying the intensity and waveform shape of the shock actually delivered to the patient's heart for a given initial pulse amplitude and duration. Pulse amplitudes and durations effective to treat low impedance patients do not necessarily deliver effective and energy efficient treatments to high impedance patients.

External defibrillators may be subjected to extreme load conditions which could potentially damage the waveform generator circuits. For example, improperly applied defibrillator electrodes may create a very low impedance current path during the shock delivery, which could result in excessively high current within the waveform circuit. Thus, an external defibrillator has an additional design requirement to limit the peak current to safe levels in the waveform circuit, which is not normally a concern for implanted defibrillators.

Prior art defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide an external defibrillator with multiple energy settings that could be selected by the user. A common protocol for using such a defibrillator was to attempt defibrillation at an initial energy setting suitable for defibrillating a patient of average impedance, then raise the energy setting for subsequent defibrillation attempts in the event that the initial setting failed. The repeated defibrillation attempts require additional energy and add to patient risk.

Some prior art defibrillators measure the patient impedance, or a parameter related to patient impedance, and alter

the shape of a subsequent defibrillation shock based on the earlier measurement. For example, the implanted defibrillator described in the Fain patent delivers a defibrillation shock of predetermined shape to the patient's heart in response to a detected arrhythmia. The Fain device measures the system impedance during delivery of that shock and uses the measured impedance to alter the shape of a subsequently delivered shock.

Another example of the measurement and use of patient impedance information in prior art defibrillators is described in an article written by R. E. Kerber, et al., "Energy, current, and success in defibrillation and cardioversion," *Circulation* (May 1988). The authors describe an external defibrillator that administers a test pulse to the patient prior to administering the defibrillation shock. The test pulse is used to measure patient impedance; the defibrillator adjusts the amount of energy delivered by the shock in response to the measured patient impedance. The shape of the delivered waveform is a damped sinusoid.

Prior art disclosures of the use of truncated exponential biphasic waveforms in implantable defibrillators have provided little guidance for the design of an external defibrillator that will achieve acceptable defibrillation or cardioversion rates across a wide population of patients. The defibrillator operating voltages and energy delivery requirements affect the size, cost, weight and availability of components. In particular, operating voltage requirements affect the choice of switch and capacitor technologies. Total energy delivery requirements affect defibrillator battery and capacitor choices. Thus, even if an implantable defibrillator and an external defibrillator both deliver waveforms of similar shape, albeit with different waveform amplitudes, the actual designs of the two defibrillators would be radically different.

SUMMARY OF THE INVENTION

This invention provides a defibrillator and defibrillation method that automatically compensates for patient-to-patient differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. The defibrillator has an energy source that may be discharged through electrodes to administer a truncated exponential biphasic voltage or current pulse to a patient.

The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform; monitoring a patient-dependent electrical parameter during the discharging step; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu. in.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic representation of a low-tilt biphasic electrotherapeutic waveform.

FIG. **2** is a schematic representation of a high-tilt biphasic electrotherapeutic waveform.

FIG. **3** is a block diagram of a defibrillator system according to a preferred embodiment of the invention.

FIG. **4** is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

FIG. **5** is an external view of a defibrillator according to a preferred embodiment of this invention.

FIG. **6** is a partial cutaway view of a defibrillator according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

For any given patient and for any given defibrillator system design, whether implantable or external, there is an optimal biphasic waveform for treating a particular kind of arrhythmia. This principle is used when implanting defibrillators; as noted above, implanted defibrillators are titrated to the patient at the time of implant. External defibrillators, on the other hand, must be designed to be effective in a wide population of patients.

For example, FIGS. **1** and **2** illustrate the patient-to-patient differences that an external defibrillator design must take into account. These figures are schematic representations of truncated exponential biphasic waveforms delivered to two different patients from an external defibrillator according to the electrotherapy method of this invention for defibrillation or cardioversion. In these drawings, the vertical axis is voltage, and the horizontal axis is time. The principles discussed here are applicable to waveforms described in terms of current versus time as well.

The waveform shown in FIG. **1** is called a low-tilt waveform, and the waveform shown in FIG. **2** is called a high-tilt waveform, where tilt H is defined as a percent as follows:

$$H = \frac{|A| - |D|}{|A|} \times 100$$

As shown in FIGS. **1** and **2**, A is the initial first phase voltage and D is the second phase terminal voltage. The first phase terminal voltage B results from the exponential decay over time of the initial voltage A through the patient, and the second phase terminal voltage D results from the exponential decay of the second phase initial voltage C in the same manner. The starting voltages and first and second phase durations of the FIG. **1** and FIG. **2** waveforms are the same; the differences in end voltages B and D reflect patient differences.

We have determined that, for a given patient, externally-applied truncated exponential biphasic waveforms defibrillate at lower voltages and at lower total delivered energies than externally-applied monophasic waveforms. In addition, we have determined that there is a complex relationship between total pulse duration, first to second phase duration ratio, initial voltage, total energy and total tilt in the delivery of an effective cardioversion waveform. Thus, it is possible to design a defibrillator and defibrillation method that is effective not only for a single patient (as in most prior art implantable defibrillators) but is also effective for a broad

population of patients. In addition, it is also possible to meet external defibrillator design requirements regarding the size, weight and capacity of the defibrillator energy source while still meeting the needs of a wide patient population.

Up to a point, the more energy delivered to a patient in an electrotherapeutic pulse, the more likely the defibrillation attempt will succeed. Low-tilt biphasic waveforms achieve effective defibrillation rates with less delivered energy than high-tilt waveforms. However, low-tilt waveforms are energy inefficient, since much of the stored energy is not delivered to the patient. On the other hand, defibrillators delivering high-tilt biphasic waveforms deliver more of the stored energy to the patient than defibrillators delivering low-tilt waveforms while maintaining high efficacy up to a certain critical tilt value. Thus, for a given capacitor, a given initial voltage and fixed phase durations, high impedance patients receive a waveform with less total energy and lower peak currents but better conversion properties per unit of energy delivered, and low impedance patients receive a waveform with more delivered energy and higher peak currents.

There appears to be an optimum tilt range in which high and low impedance patients will receive effective and efficient therapy from an external defibrillator. An optimum capacitor charged to a predetermined voltage can be chosen to deliver an effective and efficient waveform across a population of patients having a variety of physiological differences. For example, the defibrillator may operate in an open loop, i.e., without any feedback regarding patient parameters and with preset pulse phase durations which will be effective for a certain range of patients. The preset parameters of the waveforms shown in FIG. **1** and **2** are therefore the initial voltage A of the first phase of the pulse, the duration E of the first phase, the interphase duration G, and the duration F of the second phase. The terminal voltage B of the first phase, the initial voltage C of the second phase, and the terminal voltage D of the second phase are dependent upon the physiological parameters of the patient and the physical connection between the electrodes and the patient.

For example, if the patient impedance (i.e., the total impedance between the two electrodes) is high, the amount of voltage drop (exponential decay) from the initial voltage A to the terminal voltage B during time E will be lower (FIG. **1**) than if the patient impedance is low (FIG. **2**). The same is true for the initial and terminal voltages of the second phase during time F. The values of A, E, G and F are set to optimize defibrillation and/or cardioversion efficacy across a population of patients. Thus, high impedance patients receive a low-tilt waveform that is more effective per unit of delivered energy, and low impedance patients receive a high-tilt waveform that delivers more of the stored energy and is therefore more energy efficient.

In order to ensure that the delivered shock will be within the optimum tilt range for an extended range of patients, this invention provides a defibrillator method and apparatus for adjusting the characteristics of the defibrillator waveform in response to a real-time measurement of a patient-dependent electrical parameter. FIG. **3** is a block diagram showing a preferred embodiment of the defibrillator system.

The defibrillator system **30** comprises an energy source **32** to provide a voltage or current pulse. In one preferred embodiment, energy source **32** is a single capacitor or a capacitor bank arranged to act as a single capacitor.

A connecting mechanism **34** selectively connects and disconnects a pair of electrodes **36** electrically attached to a patient (represented here as a resistive load **37**) to and from the energy source. The connections between the electrodes and the energy source may be in either of two polarities with respect to positive and negative terminals on the energy source.

The defibrillator system is controlled by a controller **38**. Specifically, controller **38** operates the connecting mechanism **34** to connect energy source **32** with electrodes **36** in one of the two polarities or to disconnect energy source **32** from electrodes **36**. Controller **38** receives discharge information (such as current, charge and/or voltage) from the discharge circuit. Controller **38** may also receive timing information from a timer **40**.

Controller **38** uses information from the discharge circuit and/or the timer to control the shape of the waveform delivered to the patient in real time (i.e., during delivery of the waveform), such as by selecting appropriate waveform parameters from a memory location associated with the controller or by otherwise adjusting the duration of the phases of the biphasic waveform. By controlling the waveform shape, the system controls the duration, tilt and total delivered energy of the waveform. For example, biphasic waveforms with relatively longer first phases have better conversion properties than waveforms with equal or shorter first phases, provided the total duration exceeds a critical minimum. Therefore, in the case of high impedance patients, it may be desirable to increase the duration of the first phase of the biphasic waveform relative to the duration of the second phase to increase the overall efficacy of the electrotherapy by delivering a more efficacious waveform and to increase the total amount of energy delivered.

A preferred embodiment of a defibrillator system according to the invention is shown schematically in FIG. **4**. In this diagram, the energy source is a capacitor **32** preferably having a size between 60 and 150 microfarads, most preferably 100 microfarads. The system also includes a charging mechanism (not shown) for charging the capacitor to an initial voltage.

A controller **38** controls the operation of the defibrillator to deliver a shock to the patient **37** through electrodes **36** automatically in response to a detected arrhythmia or manually in response to a human operator. FIG. **4** shows an ECG system **50** attached to the electrodes to provide ECG monitoring and/or arrhythmia detection. FIG. **4** also shows a pair of switches **52** and **54** isolating the patient and the ECG system from the defibrillation circuitry. Switches **52** and **54** may be any suitable kind of isolators, such as mechanical relays, solid state devices, spark gaps, or other gas discharge devices. The ECG system and the isolation switches are not essential parts of this invention.

In this embodiment, the connecting mechanism **34** includes four switches **56**, **58**, **60** and **62** operated by the controller **38** to deliver a shock from the energy source **32** to the patient. The preferred embodiment also may include an optional current limiting circuit comprising a resistor **64** and switch **66** to provide additional protection to the defibrillator circuit components and to the defibrillator operator. The operation of the isolation switches and the connecting mechanism to deliver a waveform to the patient is described below.

For purposes of this description, it is assumed that all switches are open prior to discharge. It should be understood that this need not be the case. For example, switches **56**, **62** and **66** could start out in the closed position, with the operating sequence of the switches modified accordingly.

In response to a request for a shock, the controller first closes switches **52** and **54**, then switch **62**, then switch **58** to initiate delivery of a limited shock to the patient. A current sensor **68** monitors the current delivered by the capacitor. If

the peak current is below a circuit safety threshold, then switch **66** is closed to take safety resistor **64** out of the circuit. Peak current values above the threshold could indicate a short circuit condition.

In the preferred embodiment, the duration of the first and second phases of the biphasic waveform are determined by measuring a patient-dependent electrical parameter. As described in more detail below, the measured parameter in the preferred embodiment is the time it takes for a predetermined amount of charge to be delivered by the energy source to the patient. Charge control can provide better noise immunity than other waveform monitoring methods, such as voltage or current monitoring.

The system shown in FIG. 4 uses a current integrator **70** to provide charge information to the controller. The controller sets the duration of the first and second waveform phases (thereby controlling the waveform shape) based on charge information from current integrator **70**. Other means of determining phase durations may be used, of course, without departing from the scope of the invention.

At the end of the first phase of the waveform, the controller opens switch **62** to terminate delivery of the shock. Switch **66** may also be opened at any time from this point on. The controller opens switch **58** as well.

After the lapse of a brief interphase period, the controller closes switches **56** and **60** to initiate delivery of the second phase of the waveform. In the preferred embodiment the second phase duration is determined by the first phase duration. Other means of determining second phase duration are within the scope of the invention, however. At the end of the second phase, the controller opens switch **56** to terminate delivery of the shock. Switches **60**, **52** and **54** are opened thereafter.

The following example illustrates a specific implementation of the method and apparatus of this invention. The invention is not limited to the values and circuit elements discussed in this example.

In this example, switches **52** and **54** are implemented as a double pole, double throw mechanical relay. Switches **58** and **60** are each implemented as a pair of SCR's in series in order to meet required standoff voltages with currently available components. Switch **56** is implemented as two insulated gate bipolar transistors ("IGBT's") in series, again due to high voltage requirements.

The functions of switches **66** and **62** are shared among three IGBT's to meet voltage standoff requirements, with one IGBT being on at the same time as switch **66** and off at the same time as switch **62**. In this implementation resistor **64** is split into two resistors to equally divide the voltage across the IGBT's.

The current sensor **68** may be used to send current information to the controller for purposes of, e.g., short circuit protection, leads off detection, etc. The manner in which the short circuit or leads off conditions are detected are beyond the scope of this invention. The integrator **70** and current sensor **68** may each be an op-amp feeding a threshold comparator for detecting charge and Current limits, respectively. The integrator could be provided with a switch for resetting to initial conditions prior to a waveform delivery.

A comparator associated with the current integrator monitors the charge delivered to the patient and sends a signal to the waveform controller when the charge reaches 0.06182 Coulombs (referred to as "Qt"). The time required to reach that charge ("t(Qt)") is monitored by the controller using an up/down counter which counts a scaled down reference frequency. One element of the frequency scaler is a selectable 2:3 prescaler. The pre-scaler is set to 3 during the first phase. In this example, eleven time thresholds are stored in the controller, which determines the first phase duration ("t(Φ1)") based on the time required to reach Qt. At each time threshold, a new value of t(Φ1) is loaded until Qt is reached. If Qt is not reached within 6.35 mS, then t(Φ1) is set to 12 mS. The counter runs at the scaled down frequency during delivery of the entire first phase.

Some exemplary values for Qt thresholds and t(Φ1) are shown in Table I.

TABLE I

If t (Qt) < (mS)	Then t (ϕ1) is (mS)
1.13	2.3
1.60	2.85
2.07	3.79
2.56	4.02
3.07	4.83
3.58	6.76
4.10	7.73
4.64	8.69
5.20	9.66
5.77	10.62
6.35	11.59

In this example, the interphase delay is set at 300 μS. At 0 μS the first phase IGBT's are opened, terminating the first phase. At 250 μS, the second phase IGBT's are closed. At 300 μS the second phase SCR's are closed, initiating the second phase.

In this example, second phase timing is determined by first phase timing. Specifically, the count value accumulated during phase one (2.3 mS to 12 mS) is used to control the duration of the second phase. During the second phase, the counter that had been counted up during the first phase is counted down to 0, at which time the second phase is terminated. The actual duration of the second phase depends on the scaled down frequency used to run down the counter. If the first phase t(Qt) was less than 3.07 mS, then the reference clock prescaler is set to 3 to a give second phase duration equal to the first phase duration. If t(Qt) is greater than or equal to 3.07 mS, then the pre-scaler is set to 2, giving a second phase duration which is ⅔ of the first phase duration.

In an alternative embodiment, the measured patient-dependent electrical parameter is capacitor voltage. A comparator monitors the capacitor voltage and sends a signal to the waveform controller when the voltage decays to 1000 volts (Vt). As in the charge control embodiment, the time required to reach that voltage is monitored by the controller using an up/down counter which counts a scaled down reference frequency. The first phase duration (t(Φ1)) is based on the time required to reach Vt. The method of selecting the appropriate t(Φ1) is identical to the charge control embodiment. If Vt is not reached within 6.18 mS, then t(Φ1) is set to 12 mS. Table II shows the t(Vt) thresholds and their associated t(Φ1).

TABLE II

If t (Vt) < (mS)	Then t (ϕ1) is (mS)
1.24	2.3
1.73	2.85
2.23	3.79
2.72	4.02
3.22	4.83
3.71	6.76
4.20	7.73

TABLE II-continued

If t (Vt) < (mS)	Then t (φ1) is (mS)
4.70	8.69
5.19	9.66
5.69	10.62
6.18	11.59

Interphase delay and second phase timing is identical to the charge control method.

We have designed a new defibrillator meeting certain size, weight, efficacy and safety design goals. The size and weight are below the design thresholds of 150 cu. in. and four lbs. This new portable defibrillator may therefore be carried and stored in places such as drug kit boxes carried by early medical responders and in the glove boxes of cars.

The circuit design of the new defibrillator permits the use of a biphasic truncated exponential waveform, such as one of the waveforms described above. Use of the biphasic waveform permits the defibrillator to be operated with the same efficacy as prior art external defibrillators but with the storage and delivery of far less energy at lower voltages. For example, the new defibrillator effectively cardioverts patients by delivering shocks below 155 Joules of energy (167 Joules of energy stored), and most preferably on the order of 130 Joules of energy (140 Joules stored), compared with the delivery of 200–360 Joules (240–439 Joules stored) by prior art external defibrillators.

A preferred embodiment of the new external defibrillator is shown in FIGS. **5** and **6**. This defibrillator is much smaller and lighter than prior art external defibrillators. The size of the preferred defibrillator (approx. 2.2 in. ×8 in. ×8 in., for a total volume of approx. 141 cu. in.) permits it to be carried and/or stored in places in which prior art external defibrillators could not fit. In addition, its lighter weight (approx. three pounds) enables the defibrillator to be moved more easily by the operator in an emergency.

As shown in FIGS. **5** and **6**, the preferred external defibrillator includes a molded two-part plastic housing with an upper case **80** and a lower case **81**. A main printed circuit board ("PCB") **86** supports the capacitor **32**, an electrode connector **82**, a PCMCIA memory card **83** and a PCMCIA memory card ejector mechanism **84**. The PCMCIA memory card **83** lies within a PCMCIA memory card slot **95** on PCB **86**.

A keyboard PCB **85** and a display PCB **87** is disposed between the main PCB **86** and the upper case **80**. Keyboard PCB **85** interfaces with the defibrillator's operator buttons, and display PCB **87** operates the defibrillator's LCD display **88**. A display window **89** in the upper case permits display **88** to be seen by an operator.

An insulator **90** is disposed between main PCB **86** and display PCB **87**. A sealing gasket **91** lines the edges between upper case **80** and lower case **81** when the housing is assembled.

A battery assembly **99** consisting of a battery housing **92** and six lithium-manganese dioxide primary cells **94** is disposed in upper case **80** so that the batteries are in electrical contact with the capacitor charge circuits and other circuits of main PCB **86**. The battery assembly has a latching mechanism **96** for attaching and detaching the battery assembly to and from the defibrillator.

The location of the battery assembly in front of the PCMCIA memory card slot prevents the defibrillator operator or others from accessing the PCMCIA card while the defibrillator is powered up and operating. This arrangement protects the operator and patient from accidental shocks and protects the defibrillator itself from damage caused by inadvertant removal of the PCMCIA card during operation.

The small size and light weight of our defibrillator is due to a combination of a variety of design features. Use of a truncated exponential biphasic waveform instead of the prior art damped sinusoid waveform permits operation without an inductor in the waveform circuit. In addition, the lower energy requirements permit the use of a smaller capacitor and smaller batteries than those used in prior art external defibrillators.

In an effort to reduce the battery size even further, the preferred embodiment is provided with a capacitor precharge circuit and controller that begins charging the capacitor soon after the defibrillator is activated, even before ventricular fibrillation (and therefore the need for defibrillation) has been detected. The precharge voltage level is kept below the level where damage to the defibrillator circuit, the patient or the operator could occur in the event of a single fault. Thus, for example, whereas in the preferred embodiment the full preshock capacitor voltage is 1650 V, the precharge level is 1100 V. This precharge procedure minimizes the amount of energy that needs to be transferred from the battery to the capacitor when a therapeutic shock is indicated, thereby reducing the required size of the battery and the defibrillator's transformer.

The preferred embodiment uses **6** lithium-manganese dioxide primary cells instead of rechargeable batteries. Primary cells have greater energy density than rechargeable batteries and are cheaper, lighter and, since they are disposable, they are easier to maintain. While primary cells also have lower power and energy characteristics, use of a truncated exponential biphasic waveform and a capacitor precharge circuit permits operation at lower power levels.

The preferred defibrillator shown in FIGS. **5** and **6** incorporates the solid state defibrillator circuit described above with reference to FIG. **4**. Use of this circuit along with the short-circuit protection feature described above also reduces the size and weight of the defibrillator by avoiding the use of the mechanical switches required by higher voltage devices.

Other smaller and lighter-weight features of the defibrillator shown in FIGS. **5** and **6** are the use of a flat panel LCD in place of the more conventional CRT display and the use of a PCMCIA memory card to record voice and instrument information instead of a magnetic tape recorder or a paper strip chart recorder. In addition, the preferred defibrillator includes a feature whereby part of the patient ECG information stored within the PCMCIA card can be displayed on the LCD for use by a medical professional. This feature takes the place of the strip chart recorders in prior art external defibrillators.

Lightweight defibrillator electrode designs may be used to reduce the weight of the overall device even further. For example, flexible patch electrodes may be used in place of the conventional paddle electrodes. In addition, because of the lower energy and voltage features of the defibrillator, relatively thin wires may be used to attach the electrodes to the defibrillator instead of thick cables.

Other component choices and other configurations of components are within the scope of this invention as long as the threshold size and weight requirements of 150 cu. in. and four pounds are met.

Any embodiment of this invention could provide for alternating initial polarities in successive monophasic or biphasic pulses. In other words, if in the first biphasic waveform delivered by the system the first phase is a positive voltage or current pulse followed by a second phase

negative voltage or current pulse, the second biphasic waveform delivered by the system would be a negative first phase voltage or current pulse followed by a positive second phase voltage or current pulse. This arrangement would minimize electrode polarization, i.e., build-up of charge on the electrodes.

For each defibrillator method discussed above, the initial first phase voltage may be the same for all patients or it may be selected automatically or by the defibrillator user. For example, the defibrillator may have a selection of initial voltage settings, one for an infant, a second for an adult, and a third for use in open heart surgery.

In addition, while the preferred embodiment of the invention has been discussed in the context of biphasic waveforms, monophasic, triphasic or other multiphasic waveforms may be used as well. Also, patient-dependent electrical parameters other than charge delivered may be monitored and used to shape the waveform during discharge.

While the invention has been discussed with reference to external defibrillators, one or more aspects of the invention would be applicable to implantable defibrillators as well. Other modifications will be apparent to those skilled in the art.

We claim:

1. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;

monitoring a patient-dependent electrical parameter during the discharging step;

shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

2. The method of claim 1 wherein the energy source is external to the patient.

3. The method of claim 1 wherein the shaping step further comprises controlling the duration of a waveform phase based on a value of the electrical parameter.

4. The method of claim 3 wherein the shaping step further comprises controlling the duration of another phase of the waveform based on the value.

5. The method of claim 4 further comprising the step of providing a plurality of phase duration values, the shaping step comprising the step of selecting phase duration values for each phase of the multiphasic waveform from the plurality of phase duration values.

6. The method of claim 3 wherein the electrical parameter is charge delivered by the energy source to one of the electrodes.

7. The method of claim 6 wherein the discharging step begins at a discharge start time, the method further comprising the step of monitoring elapsed time from the discharge start time, the shaping step further comprising the step of determining an elapsed time value at which the charge delivered has reached a predetermined threshold.

8. The method of claim 7 wherein the shaping step further comprises selecting a first phase duration based on the elapsed time value.

9. The method of claim 8 wherein the shaping step further comprises selecting a second phase duration based on the elapsed time value.

10. The method of claim 9 wherein the second phase duration is equal to the first phase duration for at least one possible elapsed time value.

11. The method of claim 9 wherein the second phase duration is less than the first phase duration for at least one possible elapsed time value.

12. The method of claim 1 wherein the duration of the monitoring step is shorter than the duration of the discharging step.

13. The method of claim 1 wherein the shaping step is performed without the use of an inductor.

14. The method of claim 1 wherein the initial level is an initial discharge level, the method further comprising the step of precharging the energy source to a level less than the initial discharge level prior to the step of charging the energy source to the initial discharge level.

15. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform;

monitoring an electrical parameter during the discharging step;

adjusting the tilt of the waveform based on the value of the monitored electrical parameter, the adjusting step comprising controlling the duration of a waveform phase based on a value of the electrical parameter wherein the relative duration of the phases of the waveform is dependent on the value of the monitored electrical parameter.

16. An apparatus for administering electrotherapy to a patient's heart through electrodes external to the patient comprising:

an energy source;

two electrodes adapted to make electrical contact with a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; an electrical parameter monitor; and

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a truncated exponential multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy.

17. The apparatus of claim 16 wherein the connecting mechanism comprises a plurality of switches for selectively directing electrical energy from the energy source to the patient in one of two polarities.

18. The apparatus of claim 17 wherein the electrical parameter monitor comprises a charge sensor providing information to the controller related to charge delivered by the energy source to the electrodes.

19. The apparatus of claim 18 further comprising a timer associated with the charge sensor and the controller.

20. The apparatus of claim 19 wherein the controller comprises a counter with a controllable counting rate, the counter being adapted to count in one direction during delivery of a first phase of the multiphasic waveform and in another direction during delivery of a second phase of the multiphasic waveform.

21. The apparatus of claim 16 further comprising means for selectively limiting current flow through the electrodes and means for determining whether current flowing to the electrodes is below a predetermined threshold.

22. The apparatus of claim 21 wherein the means for selectively limiting current flow comprises an impedance

and a shunting switch in the circuit with the electrodes and the energy source.

23. The apparatus of claim 16 wherein the energy source comprises a battery disposed in a battery holder, the apparatus further comprising a solid state memory device disposed in a memory device holder, the battery blocking external access to the memory device when the battery is disposed in the battery holder.

24. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes; and

a housing containing at least the energy source, the connecting mechanism and the controller, the housing having a volume less than 150 cubic inches.

25. The defibrillator of claim 24 in which the housing has a first dimension not greater than 2.2 inches.

26. The defibrillator of claim 25 in which the housing has second and third dimensions not greater than 8 inches.

27. The defibrillator of claim 24 wherein the energy source comprises primary cell batteries.

28. The defibrillator of claim 27 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

29. The defibrillator of claim 24 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

30. The defibrillator of claim 24 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

31. The defibrillator of claim 24 further comprising an ECG system.

32. The defibrillator of claim 31 further comprising an LCD display.

33. The defibrillator of claim 32 further comprising a PCMCIA memory card.

34. The defibrillator of claim 33 further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

35. The defibrillator of claim 24 wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads.

36. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes;

the defibrillator having a weight less than four pounds.

37. The defibrillator of claim 36 wherein the energy source comprises primary cell batteries.

38. The defibrillator of claim 37 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

39. The defibrillator of claim 36 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

40. The defibrillator of claim 36 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

41. The defibrillator of claim 36 further comprising an ECG system.

42. The defibrillator of claim 41 further comprising an LCD display.

43. The defibrillator of claim 42 further comprising a PCMCIA memory card.

44. The defibrillator of claim 43 further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

45. The defibrillator of claim 36 wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads.

46. A method for applying electrotherapy to a patient from an energy source external to the patient, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source to deliver electrical energy to the patient in a multiphasic waveform;

determining the time during which a predetermined amount of charge is delivered to the patient;

shaping the waveform of the delivered electrical energy based on the value of the determined time, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the determined time.

47. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

maintaining the charge of the energy source at the initial level;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient.

48. The method of claim 47 wherein the initial level is below a charge level that could harm a patient.

49. The method of claim 47 wherein the first charging step is performed in response to activation of a defibrillator.

50. The method of claim 47 wherein the discharging step comprises the step of discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

51. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a waveform, the patient and an additional impedance forming an electrical circuit with the energy source;

monitoring an electrical parameter during the discharging step;

removing the additional impedance from the electrical circuit if the electrical parameter is within a defined range prior to the end of the discharging step.

52. The method of claim 51 wherein the removing step comprises operating a switch associated with the additional impedance.

53. A method for applying electrotherapy to a patient comprising the following steps:

discharging an energy source across electrodes to deliver a waveform of electrical energy to the patient;

monitoring a patient-dependent electrical parameter during the discharge step;

ceasing the monitoring step prior to the end of the discharge step;

adjusting a waveform discharge parameter based on a value of the monitored parameter.

54. The method of claim **53** wherein discharging step and the monitoring step begin substantially simultaneously.

55. The method of claim **53** wherein the monitored parameter is time for delivering a predetermined quantity of charge to the patient.

56. The method of claim **55** wherein the discharge parameter is waveform duration.

57. The method of claim **55** wherein the waveform is a biphasic waveform and the discharge parameter is duration of a waveform phase.

58. A method for applying electrotherapy to a patient through electrodes attached to an energy source, the method comprising the following steps:

charging the energy source to an initial level prior to detecting a need to apply a shock to a patient;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

59. The method of claim **58** wherein the first charging step is performed in response to activation of a defibrillator.

* * * * *

Exhibit-3

1:10-cv-11041-NMG

US005749905A

United States Patent [19]

Gliner et al.

[11] **Patent Number: 5,749,905**

[45] **Date of Patent: *May 12, 1998**

[54] **ELECTROTHERAPY METHOD UTILIZING PATIENT DEPENDENT ELECTRICAL PARAMETERS**

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[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,601,612.

[21] Appl. No.: **691,755**

[22] Filed: **Aug. 2, 1996**

Related U.S. Application Data

[63] Continuation of Ser. No. 103,837, Aug. 6, 1993, abandoned.

[51] **Int. Cl.**[6] **A61N 1/39**

[52] **U.S. Cl.** **607/7**; 607/74

[58] **Field of Search** 607/4, 5, 6, 7, 607/8, 2, 39, 40, 42, 43–46, 48, 50, 58, 62, 74

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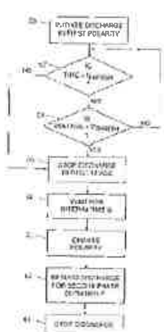
[57] **ABSTRACT**

This invention provides an external defibrillator and defibrillation method that automatically compensates for patient-to-patient impedance differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. In a preferred embodiment, the defibrillator has an energy source that may be discharged through electrodes on the patient to provide a biphasic voltage or current pulse. In one aspect of the invention, the first and second phase duration and initial first phase amplitude are predetermined values. In a second aspect of the invention, the duration of the first phase of the pulse may be extended if the amplitude of the first phase of the pulse fails to fall to a threshold value by the end of the predetermined first phase duration, as might occur with a high impedance patient. In a third aspect of the invention, the first phase ends when the first phase amplitude drops below a threshold value or when the first phase duration reaches a threshold time value, whichever comes first, as might occur with a low to average impedance patient. This method and apparatus of altering the delivered biphasic pulse thereby compensates for patient impedance differences by changing the nature of the delivered electrotherapeutic pulse, resulting in a smaller, more efficient and less expensive defibrillator.

11 Claims, 7 Drawing Sheets



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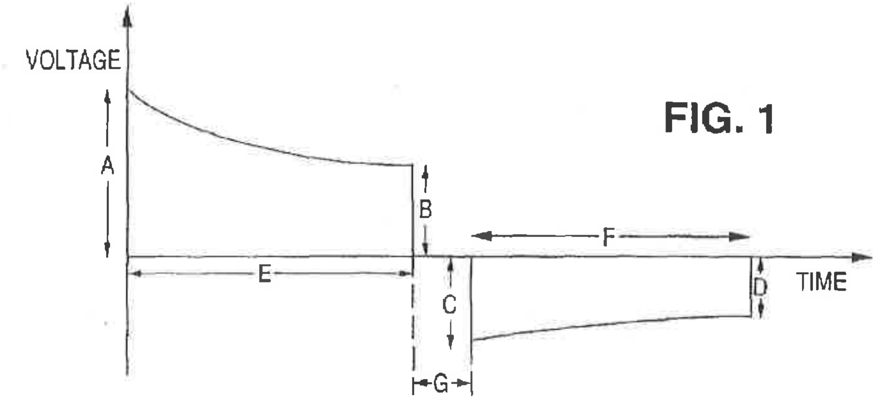


FIG. 1

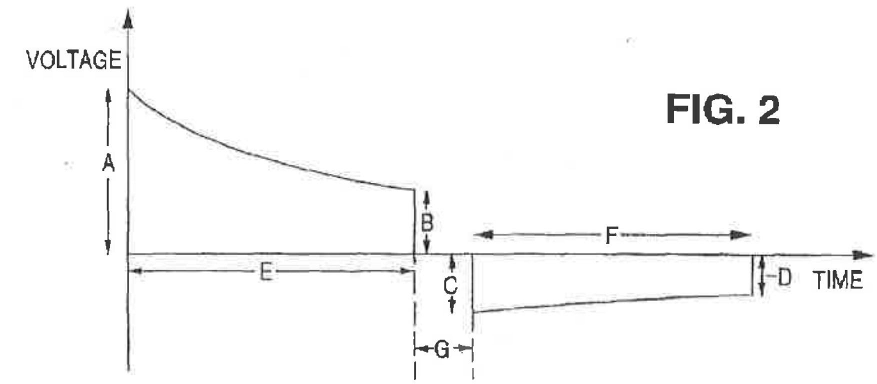


FIG. 2

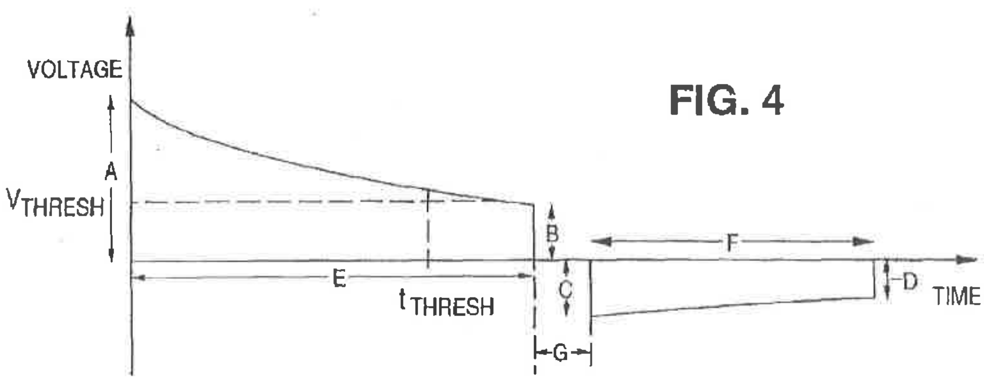
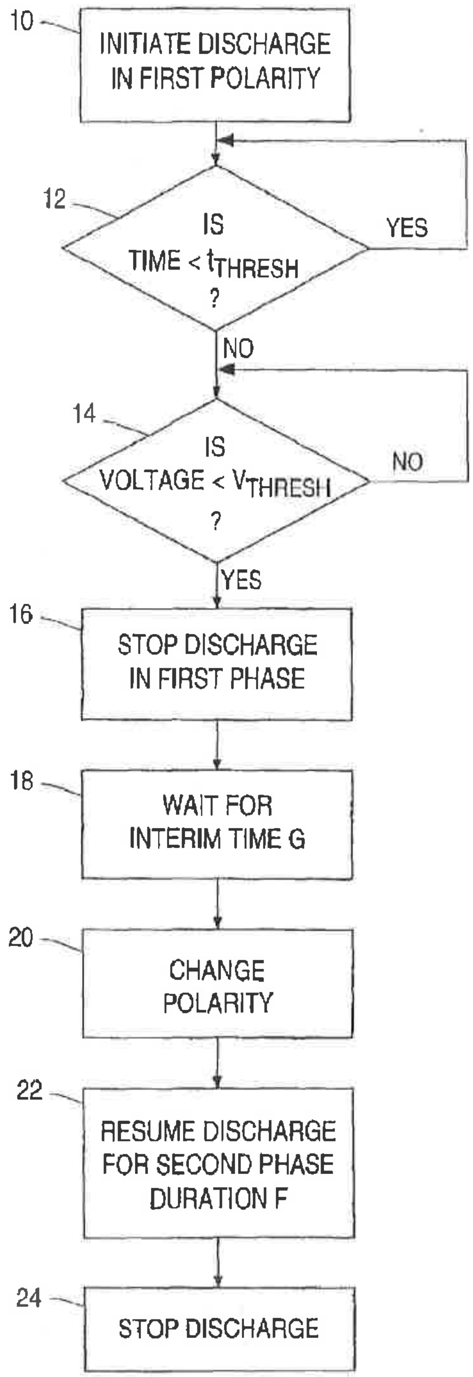


FIG. 4



10
INITIATE DISCHARGE IN FIRST POLARITY
12
IS TIME < t_{THRESH} ?
YES
NO
14
IS VOLTAGE < V_{THRESH} ?
NO
YES
16
STOP DISCHARGE IN FIRST PHASE
18
WAIT FOR INTERIM TIME G
20
CHANGE POLARITY
22
RESUME DISCHARGE FOR SECOND PHASE DURATION F
24
STOP DISCHARGE

FIG. 3

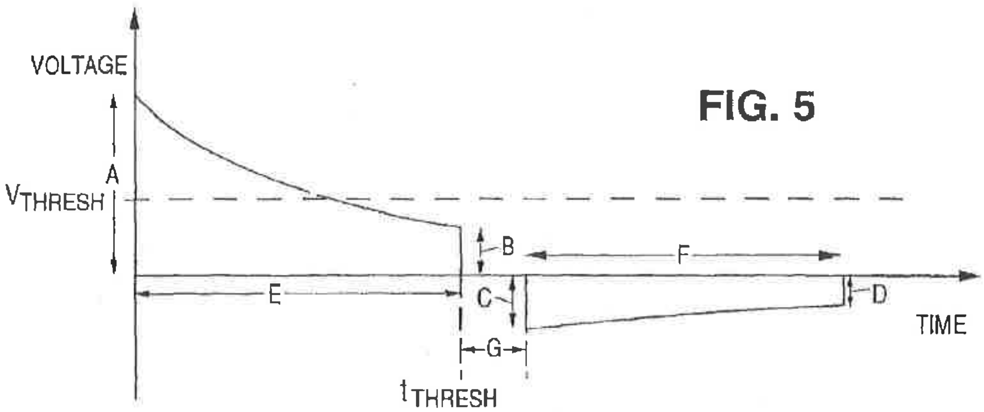


FIG. 5

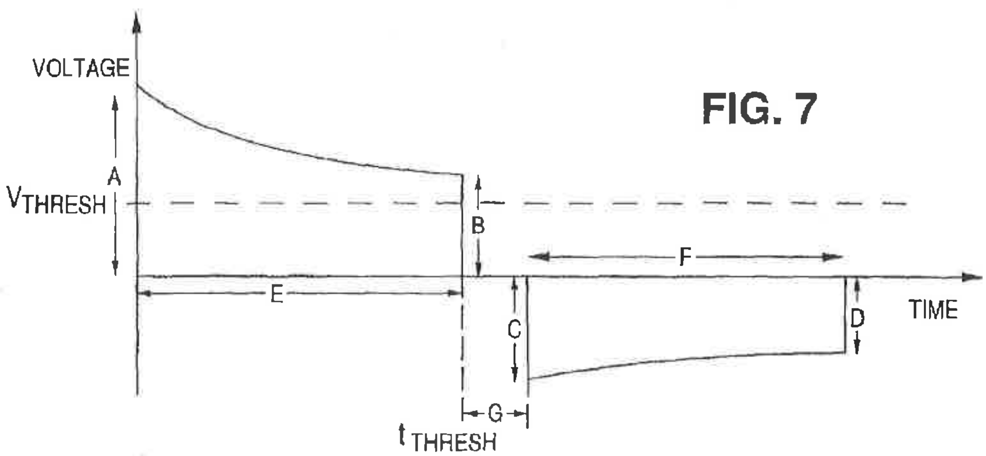


FIG. 7

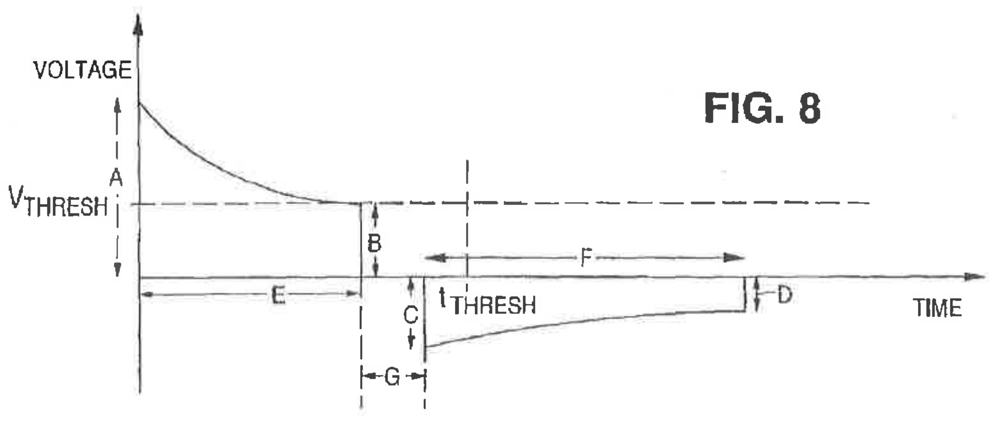
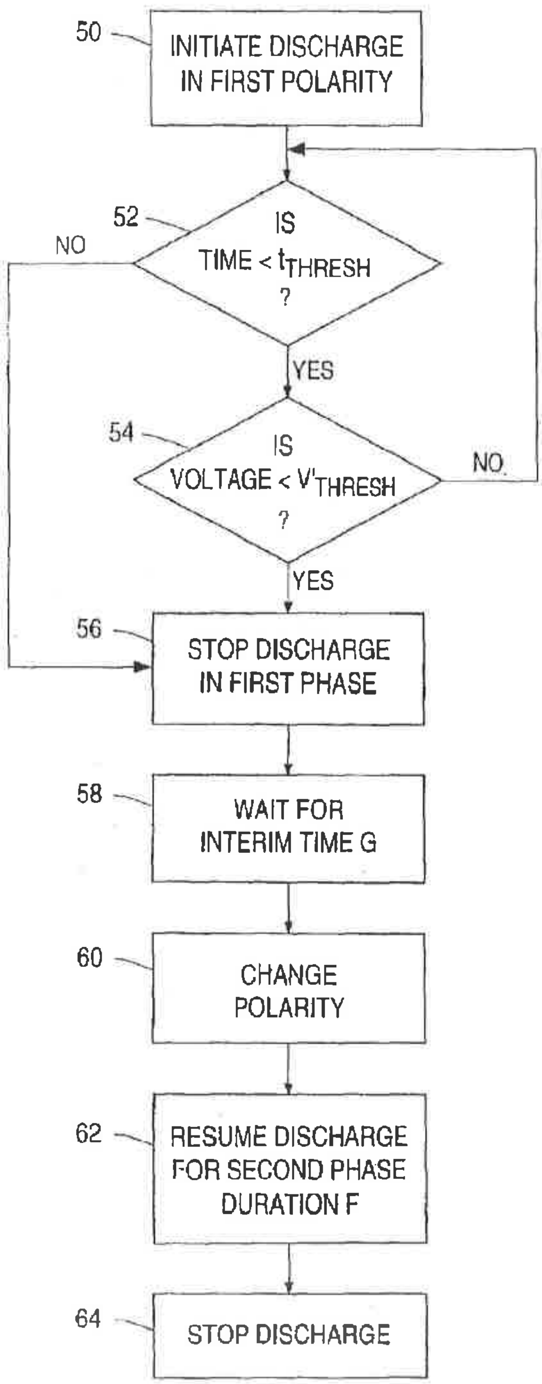
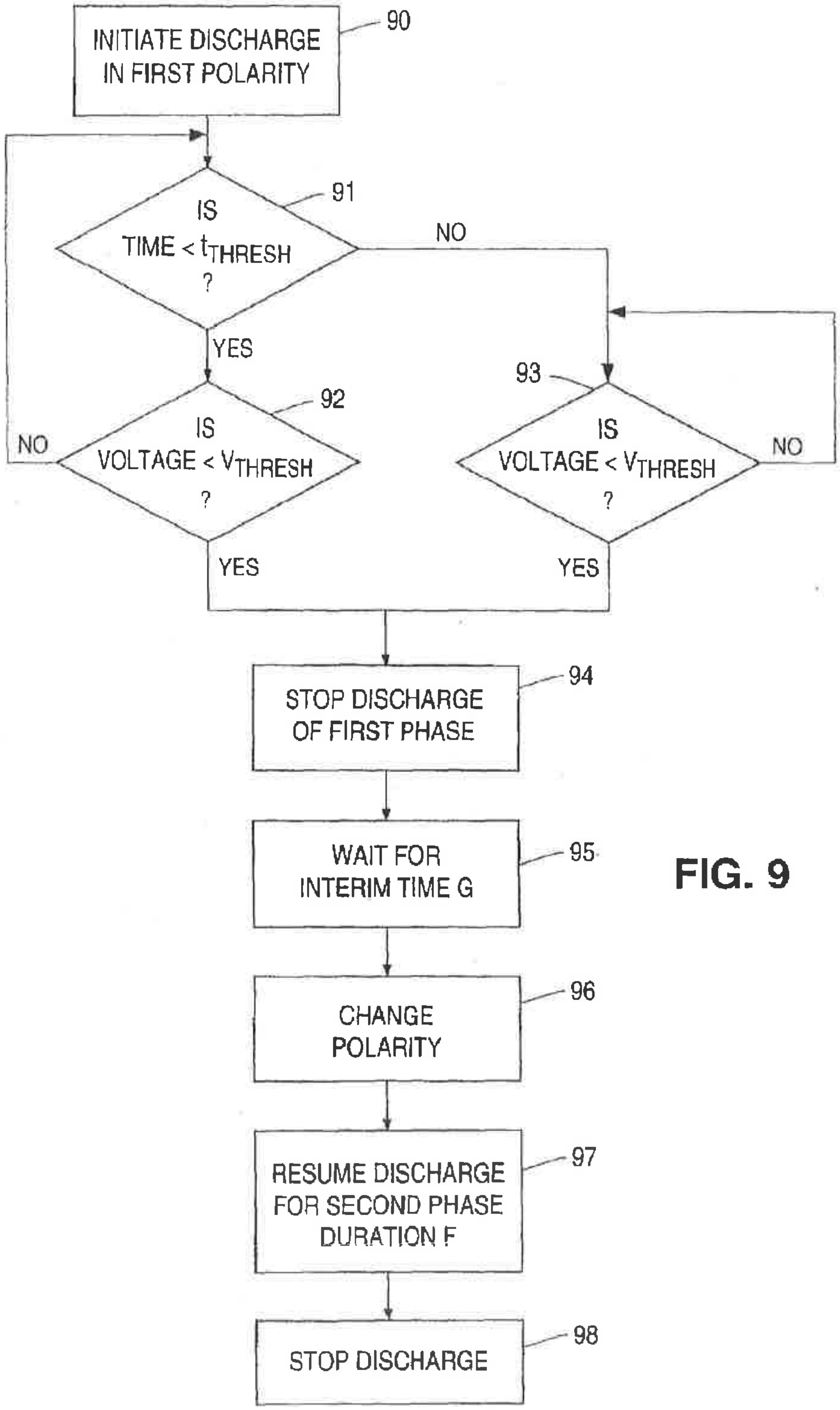


FIG. 8



50
INITIATE DISCHARGE IN FIRST POLARITY
52
NO
IS TIME < t_{THRESH} ?
YES
54
IS VOLTAGE < V'_{THRESH} ?
NO
YES
56
STOP DISCHARGE IN FIRST PHASE
58
WAIT FOR INTERIM TIME G
60
CHANGE POLARITY
62
RESUME DISCHARGE FOR SECOND PHASE DURATION F
64
STOP DISCHARGE

FIG. 6



INITIATE DISCHARGE IN FIRST POLARITY
90
IS TIME < t_{THRESH} ?
91
NO
YES
IS VOLTAGE < V_{THRESH} ?
92
NO
YES
93
IS VOLTAGE < V_{THRESH} ?
NO
YES
STOP DISCHARGE OF FIRST PHASE
94
WAIT FOR INTERIM TIME G
95
CHANGE POLARITY
96
RESUME DISCHARGE FOR SECOND PHASE DURATION F
97
STOP DISCHARGE
98

FIG. 9

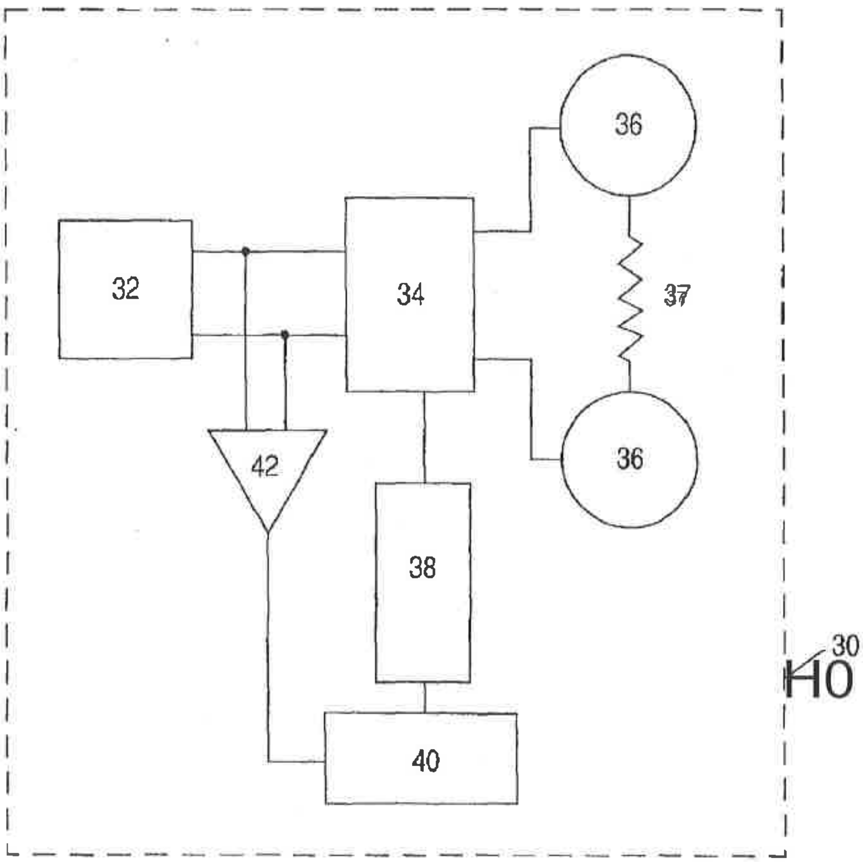


FIG. 10

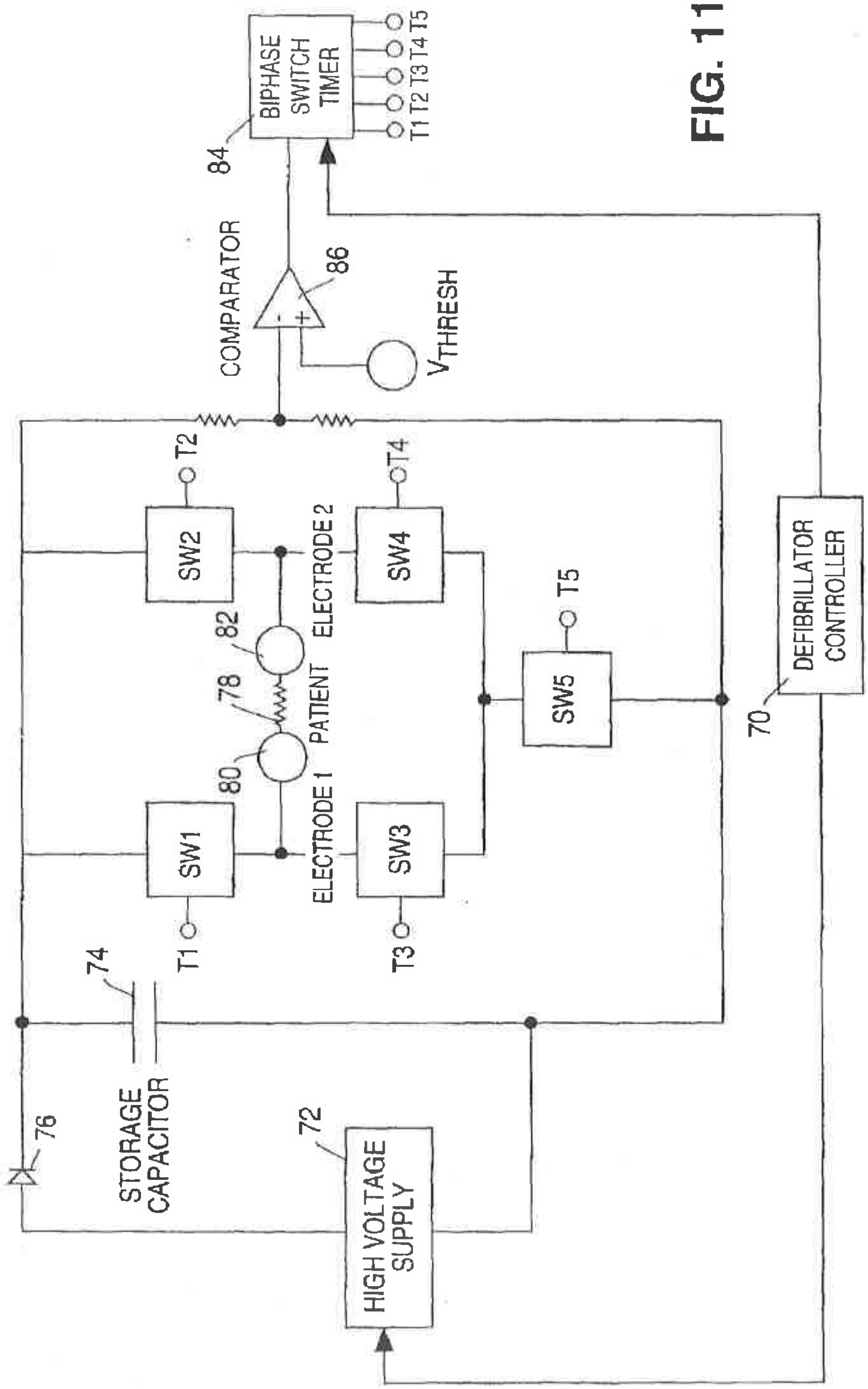


FIG. 11

PHI00073767

Exhibit-3.00010

ELECTROTHERAPY METHOD UTILIZING PATIENT DEPENDENT ELECTRICAL PARAMETERS

This application is a CONTINUATION of application Ser. No. 08/103,837 filed Aug. 6, 1993 now abandoned.

BACKGROUND OF THE INVENTION

This invention relates generally to an electrotherapy method and apparatus for delivering a shock to a patient's heart. In particular, this invention relates to a method and apparatus for using an external defibrillator to deliver a biphasic defibrillation shock to a patient's heart through electrodes attached to the patient.

Defibrillators apply pulses of electricity to a patient's heart to convert ventricular arrhythmias, such as ventricular fibrillation and ventricular tachycardia, to normal heart rhythms through the processes of defibrillation and cardioversion, respectively. There are two main classifications of defibrillators: external and implanted. Implantable defibrillators are surgically implanted in patients who have a high likelihood of needing electrotherapy in the future. Implanted defibrillators typically monitor the patient's heart activity and automatically supply electrotherapeutic pulses directly to the patient's heart when indicated. Thus, implanted defibrillators permit the patient to function in a somewhat normal fashion away from the watchful eye of medical personnel.

External defibrillators send electrical pulses to the patient's heart through electrodes applied to the patient's torso. External defibrillators are useful in the emergency room, the operating room, emergency medical vehicles or other situations where there may be an unanticipated need to provide electrotherapy to a patient short notice. The advantage of external defibrillators is that they may be used on a patient as needed, then subsequently moved to be used with another patient. However, because external defibrillators deliver their electrotherapeutic pulses to the patient's heart indirectly (i.e., from the surface of the patient's skin rather than directly to the heart), they must operate at higher energies, voltages and/or currents than implanted defibrillators. The high energy, voltage and current requirements have made current external defibrillators large, heavy and expensive, particularly due to the large size of the capacitors or other energy storage media required by these prior art devices.

The time plot of the current or voltage pulse delivered by a defibrillator shows the defibrillator's characteristic waveform. Waveforms are characterized according to the shape, polarity, duration and number of pulse phases. Most current external defibrillators deliver monophasic current or voltage electrotherapeutic pulses, although some deliver biphasic sinusoidal pulses. Some prior art implantable defibrillators, on the other hand, use truncated exponential, biphasic waveforms. Examples of biphasic implantable defibrillators may be found in U.S. Pat. No. 4,821,723 to Baker, Jr., et al.; U.S. Pat. No. 5,083,562 to de Coriolis et al.; U.S. Pat. No. 4,800,883 to Winstrom; U.S. Pat. No. 4,850,357 to Bach, Jr.; and U.S. Pat. No. 4,953,551 to Mehra et al.

Because each implanted defibrillator is dedicated to a single patient, its operating parameters, such as electrical pulse amplitudes and total energy delivered, may be effectively titrated to the physiology of the patient to optimize the defibrillator's effectiveness. Thus, for example, the initial voltage, first phase duration and total pulse duration may be set when the device is implanted to deliver the desired amount of energy or to achieve that desired start and end voltage differential (i.e, a constant tilt).

In contrast, because external defibrillator electrodes are not in direct contact with the patient's heart, and because external defibrillators must be able to be used on a variety of patients having a variety of physiological differences, external defibrillators must operate according to pulse amplitude and duration parameters that will be effective in most patients, no matter what the patient's physiology. For example, the impedance presented by the tissue between external defibrillator electrodes and the patient's heart varies from patient to patient, thereby varying the intensity and waveform shape of the shock actually delivered to the patient's heart for a given initial pulse amplitude and duration. Pulse amplitudes and durations effective to treat low impedance patients do not necessarily deliver effective and energy efficient treatments to high impedance patients.

Prior art external Defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide the external defibrillator with multiple energy settings that could be selected by the user. A common protocol for using such a defibrillator was to attempt defibrillation at an initial energy setting suitable for defibrillating a patient of average impedance, then raise the energy setting for subsequent defibrillation attempts in the event that the initial setting failed. The repeated defibrillation attempts require additional energy and add to patient risk. What is needed, therefore, is an external defibrillation method and apparatus that maximizes energy efficiency (to minimize the size of the required energy storage medium) and maximizes therapeutic efficacy across an entire population of patients.

SUMMARY OF THE INVENTION

This invention provides an external defibrillator and defibrillation method that automatically compensates for patient-to-patient impedance differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. In a preferred embodiment, the defibrillator has an energy source that may be discharged through electrodes on the patient to provide a biphasic voltage or current pulse. In one aspect of the invention, the first and second phase duration and initial first phase amplitude are predetermined values. In a second aspect of the invention, the duration of the first phase of the pulse may be extended if the amplitude of the first phase of the pulse fails to fall to a threshold value by the end of the predetermined first phase duration, as might occur with a high impedance patient. In a third aspect of the invention, the first phase ends when the first phase amplitude drops below a threshold value or when the first phase duration reaches a threshold time value, whichever comes first, as might occur with a low to average impedance patient. This method and apparatus of altering the delivered biphasic pulse thereby compensates for patient impedance differences by changing the nature of the delivered electrotherapeutic pulse, resulting in a smaller, more efficient and less expensive defibrillator.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of a low-tilt biphasic electrotherapeutic waveform according to a first aspect of this invention.

FIG. 2 is a schematic representation of a high-tilt biphasic electrotherapeutic waveform according to the first aspect of this invention.

FIG. 3 is a flow chart demonstrating part of an electrotherapy method according to a second aspect of this invention.

FIG. 4 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

FIG. 5 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

FIG. 6 is a flow chart demonstrating part of an electrotherapy method according to a third aspect of this invention.

FIG. 7 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

FIG. 8 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

FIG. 9 is a flow chart demonstrating part of an electrotherapy method according to a combination of the second and third aspects of this invention.

FIG. 10 is a block diagram of a defibrillator system according to a preferred embodiment of this invention.

FIG. 11 is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. 1 and 2 illustrate the patient-to-patient differences that an external defibrillator design must take into account. These figures are schematic representations of truncated exponential biphasic waveforms delivered to two different patients from an external defibrillator according to the electrotherapy method of this invention for defibrillation or cardioversion. In these drawings, the vertical axis is voltage, and the horizontal axis is time. The principles discussed here are applicable to waveforms described in terms of current versus time as well, however.

The waveform shown in FIG. 1 is called a low-tilt waveform, and the waveform shown in FIG. 2 is called a high-tilt waveform, where tilt H is defined as a percent as follows:

$$H = \frac{|A| - |D|}{|A|} \times 100$$

As shown in FIGS. 1 and 2, A is the initial first phase voltage and D is the second phase terminal voltage. The first phase terminal voltage B results from the exponential decay over time of the initial voltage A through the patient, and the second phase terminal voltage D results from the exponential decay of the second phase initial voltage C in the same manner. The starting voltages and first and second phase durations of the FIG. 1 and FIG. 2 waveforms are the same; the differences in end voltages B and D reflect differences in patient impedance.

Prior art disclosures of the use of truncated exponential biphasic waveforms in implantable defibrillators have provided little guidance for the design of an external defibrillator that will achieve acceptable defibrillation or cardioversion rates across a wide population of patients. The defibrillator operating voltages and energy delivery requirements affect the size, cost, weight and availability of components. In particular, operating voltage requirements affect the choice of switch and capacitor technologies. Total energy delivery requirements affect defibrillator battery and capacitor choices.

We have determined that, for a given patient, externally-applied truncated exponential biphasic waveforms defibrillate at lower voltages and at lower total delivered energies than externally-applied monophasic waveforms. In addition, we have determined that there is a complex relationship between total pulse duration, first to second phase duration ratio, initial voltage, total energy and total tilt.

Up to a point, the more energy delivered to a patient in an electrotherapeutic pulse, the more likely the defibrillation attempt will succeed. Low-tilt biphasic waveforms achieve effective defibrillation rates with less delivered energy than high-tilt waveforms. However, low-tilt waveforms are energy inefficient, since much of the stored energy is not delivered to the patient. On the other hand, defibrillators delivering high-tilt biphasic waveforms deliver more of the stored energy to the patient than defibrillators delivering low-tilt waveforms while maintaining high efficacy up to a certain critical tilt value. Thus, for a given capacitor, a given initial voltage and fixed phase durations, high impedance patients receive a waveform with less total energy and lower peak currents but better conversion properties per unit of energy delivered, and low impedance patients receive a waveform with more delivered energy and higher peak currents. There appears to be an optimum tilt range in which high and low impedance patients will receive effective and efficient therapy. An optimum capacitor charged to a predetermined voltage can be chosen to deliver an effective and efficient waveform across a population of patients having a variety of physiological differences.

This invention is a defibrillator and defibrillation method that takes advantage of this relationship between waveform tilt and total energy delivered in high and low impedance patients. In one aspect of the invention, the defibrillator operates in an open loop, i.e., without any feedback regarding patient impedance parameters and with preset pulse phase durations. The preset parameters of the waveforms shown in FIGS. 1 and 2 are therefore the initial voltage A of the first phase of the pulse, the duration E of the first phase, the interphase duration G, and the duration F of the second phase. The terminal voltage B of the first phase, the initial voltage C of the second phase, and the terminal voltage D of the second phase are dependent upon the physiological parameters of the patient and the physical connection between the electrodes and the patient.

For example, if the patient impedance (i.e., the total impedance between the two electrodes) is high, the amount of voltage drop (exponential decay) from the initial voltage A to the terminal voltage B during time E will be lower (FIG. 1) than if the patient impedance is low (FIG. 2). The same is true for the initial and terminal voltages of the second phase during time F. The values of A, E, G and F are set to optimize defibrillation and/or cardioversion efficacy across a population of patients. Thus, high impedance patients receive a low-tilt waveform that is more effective per unit of delivered energy, and low impedance patients receive a high-tilt waveform that delivers more of the stored energy and is therefore more energy efficient.

Another feature of biphasic waveforms is that waveforms with relatively longer first phases have better conversion properties than waveforms with equal or shorter first phases, provided the total duration exceeds a critical minimum. Therefore, in the case of high impedance patients, it may be desirable to extend the first phase of the biphasic waveform (while the second phase duration is kept constant) to increase the overall efficacy of the electrotherapy by delivering a more efficacious waveform and to increase the total amount of energy delivered. FIGS. 3–5 demonstrate a defibrillation method according to this second aspect of the invention in which information related to patient impedance is fed back to the defibrillator to change the parameters of the delivered electrotherapeutic pulse.

FIG. 3 is a flow chart showing the method steps following the decision (by an operator or by the defibrillator itself) to apply an electrotherapeutic shock to the patient through electrodes attached to the patient and charging of the energy source, e.g., the defibrillator's capacitor or capacitor bank, to the initial first phase voltage A. Block 10 represents initiation of the first phase of the pulse in a first polarity. Discharge may be initiated manually by the user or automatically in response to patient heart activity measurements (e.g., ECG signals) received by the defibrillator through the electrodes and analyzed by the defibrillator controller in a manner known in the art.

Discharge of the first phase continues for at least a threshold time t_{THRESH}, as shown by block 12 of FIG. 3. If, at the end of time t_{THRESH}, the voltage measured across the energy source has not dropped below the minimum first phase terminal voltage threshold V_{THRESH}, first phase discharge continues, as shown in block 14 of FIG. 3. For high impedance patients, this situation results in an extension of the first phase duration beyond t_{THRESH}, as shown in FIG. 4, until the measured voltage drops below the threshold V_{THRESH}. Discharge then ends to complete the first phase, as represented by block 16 of FIG. 3. If, on the other hand, the patient has low impedance, the voltage will have dropped below V_{THRESH} when the time threshold is reached, resulting in a waveform like the one shown in FIG. 5.

At the end of the first phase, and after a predetermined interim period G, the polarity of the energy source connection to the electrodes is switched, as represented by blocks 18 and 20 of FIG. 3. Discharge of the second phase of the biphasic pulse then commences and continues for a predetermined second phase duration F, as represented by block 22 of FIG. 3, then ceases. This compensating electrotherapy method ensures that the energy is delivered by the defibrillator in the most efficacious manner by providing for a minimum waveform tilt and by extending the first phase duration to meet the requirements of a particular patient.

Because this method increases the waveform tilt for high impedance patients and delivers more of the energy from the energy source than a method without compensation, the defibrillator's energy source can be smaller than in prior art external defibrillators, thereby minimizing defibrillator size, weight and expense. It should be noted that the waveforms shown in FIGS. 4 and 5 could be expressed in terms of current versus time using a predetermined current threshold value without departing from the scope of the invention.

FIGS. 6–8 illustrate a third aspect of this invention that prevents the delivered waveform from exceeding a maximum tilt (i.e., maximum delivered energy) in low impedance patients. As shown by blocks 52 and 54 in FIG. 6, the first phase discharge stops either at the end of a predetermined time t_{THRESH} or when the first phase voltage drops below V'_{THRESH}. The second phase begins after an interim period G and continues for a preset period F as in the second aspect of the invention. Thus, in high impedance patients, the first phase ends at time t_{THRESH}, even if the voltage has not yet fallen below V'_{THRESH}, as shown in FIG. 7. In low impedance patients, on the other hand, the first phase of the delivered waveform could be shorter in duration than the time t_{THRESH}, as shown in FIG. 8.

Once again, the waveforms shown in FIGS. 7 and 8 could be expressed in terms of current versus time using a predetermined current threshold value without departing from the scope of the invention.

FIG. 9 is a flow chart illustrating a combination of the defibrillation methods illustrated in FIGS. 3 and 6. In this combination method, the first phase of the biphasic waveform will end if the voltage reaches a first voltage threshold V'_{THRESH} prior to the first phase duration threshold t_{THRESH}, as shown by blocks 91 and 92. This defibrillator decision path delivers a waveform like that shown in FIG. 8 for low impedance patients. For high impedance patients, on the other hand, if at the expiration of t_{THRESH} the voltage has not fallen below V'_{THRESH}, the duration of the first phase is extended beyond t_{THRESH} until the voltage measured across the electrodes reaches a second voltage threshold V_{THRESH}, as shown in decision blocks 91 and 93. This defibrillator method path will deliver a waveform like that shown in FIG. 4.

In alternative embodiments of this invention, the second phase pulse could be a function of the first phase voltage, current or time instead of having a fixed time duration. In addition, any of the above embodiments could provide for alternating initial polarities in successive monophasic or biphasic pulses. In other words, if in the first biphasic waveform delivered by the system the first phase is a positive voltage or current pulse followed by a second phase negative voltage or current pulse, the second biphasic waveform delivered by the system would be a negative first phase voltage or current pulse followed by a positive second phase voltage or current pulse. This arrangement would minimize electrode polarization, i.e., build-up of charge on the electrodes.

For each defibrillator method discussed above, the initial first phase voltage A may be the same for all patients or it may be selected automatically or by the defibrillator user. For example, the defibrillator may have a selection of initial voltage settings, one for an infant, a second for an adult, and a third for use in open heart surgery.

FIG. 10 is a schematic block diagram of a defibrillator system according to a preferred embodiment of this invention. The defibrillator system 30 comprises an energy source 32 to provide the voltage or current pulses described above. In one preferred embodiment, energy source 32 is a single capacitor or a capacitor bank arranged to act as a single capacitor. A connecting mechanism 34 selectively connects and disconnects energy source 32 to and from a pair of electrodes 36 electrically attached to a patient, represented here as a resistive load 37. The connections between the electrodes and the energy source may be in either of two polarities with respect to positive and negative terminals on the energy source.

The defibrillator system is controlled by a controller 38. Specifically, controller 38 operates the connecting mechanism 34 to connect energy source 32 with electrodes 36 in one of the two polarities or to disconnect energy source 32 from electrodes 36. Controller 38 receives timing information from a timer 40, and timer 40 receives electrical information from electrical sensor 42 connected across energy source 32. In some preferred embodiments, sensor 42 is a voltage sensor; in other preferred embodiments, sensor 42 is a current sensor.

FIG. 11 is a schematic circuit diagram illustrating a device according to the preferred embodiments discussed above. Defibrillator controller 70 activates a high voltage power supply 72 to charge storage capacitor 74 via diode 76 to a predetermined voltage. During this period, switches SW1, SW2, SW3 and SW4 are turned off so that no voltage is applied to the patient (represented here as resistor 78) connected between electrodes 80 and 82. SW5 is turned on during this time.

After charging the capacitor, controller 70 deactivates supply 72 and activates biphase switch timer 84. Timer 84 initiates discharge of the first phase of the biphasic wave-

form through the patient in a first polarity by simultaneously turning on switches SW1 and SW4 via control signals T1 and T4, while switch SW5 remains on to deliver the initial voltage A through electrodes 80 and 82 to the patient 78.

Depending on the operating mode, delivery of the first phase of the biphasic pulse may be terminated by the timer 84 after the end of a predetermined period or when the voltage across the electrodes has dropped below a predetermined value as measured by comparator 86. Timer 84 terminates pulse delivery by turning off switch SW5 via control signal T5, followed by turning off switches SW1 and SW4. The voltage across electrodes 80 and 82 then returns to zero.

During the interim period G, SW5 is turned on to prepare for the second phase. After the end of interim period G, timer 84 initiates delivery of the second phase by simultaneously turning on switches SW2 and SW3 via control signals T2 and T3 while switch SW5 remains on. This configuration applies voltage from the capacitor to the electrodes at an initial second phase voltage C and in a polarity opposite to the first polarity. Timer 84 terminates delivery of the second phase by turning off switch SW5 via control signal T5, followed by turning off switches SW2 and SW3. The second phase may be terminated at the end of a predetermined period or when the voltage measured by comparator 86 drops below a second phase termination voltage threshold.

In a preferred embodiment, switch SW5 is an insulated gate bipolar transistor (IGBT) and switches SW1–SW4 are silicon-controlled rectifiers (SCRs). The SCRs are avalanche-type switches which can be turned on to a conductive state by the application of a control signal, but cannot be turned off until the current through the switch falls to zero or near zero. Thus, the five switches can be configured so that any of the switches SW1–SW4 will-close when SW5 is closed and will reopen only upon application of a specific control signal to SW5.

This design has the further advantage that switch SW5 does not need to withstand the maximum capacitor voltage. The maximum voltage that will be applied across switch SW5 will occur when the first phase is terminated by turning SW5 off, at which time the capacitor voltage has decayed to some fraction of its initial value.

Other switches and switch configurations may be used, of course without departing from the scope of the invention. In addition, the defibrillator configurations of FIGS. 10 and 11 may be used to deliver electric pulses of any polarity, amplitude, and duration singly and in any combination.

While the invention has been discussed with reference to external defibrillators, one or more aspects of the invention would be applicable to implantable defibrillators as well. Other modifications will be apparent to those skilled in the art.

What is claimed is:

1. A method for delivering electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

discharging the energy source across the electrodes to deliver electrical energy to the patient;

monitoring a patient-dependent electrical parameter during the discharging step;

adjusting energy delivered to the patient based on a value of the electrical parameter.

2. The method of claim 1 wherein the energy source comprises a capacitor, the discharging step comprising discharging the capacitor across the electrodes to deliver electrical energy to the patient in a waveform having more than one phase.

3. The method of claim 1 wherein the energy source comprises a plurality of capacitors, the discharging step comprising discharging the plurality of capacitors across the electrodes to deliver energy to the patient in a waveform having more than one phase.

4. A method for delivering electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;

monitoring a patient-dependent electrical parameter during the discharging step;

shaping the waveform so that an initial parameter of a waveform phase depends on a value of the electrical parameter.

5. The method of claim 4 wherein the energy source comprises a capacitor, the discharging step comprising discharging the capacitor across the electrodes to deliver electrical energy to the patient.

6. The method of claim 4 wherein the energy source comprises a plurality of capacitors, the discharging step comprising discharging the plurality of capacitors across the electrodes to deliver energy to the patient.

7. The method of claim 4 wherein the initial parameter is voltage.

8. The method of claim 4 wherein the initial parameter is current.

9. A method for delivering electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;

monitoring a patient-dependent electrical parameter during the discharging step;

shaping the waveform so that an ending parameter of a waveform phase depends on a value of the electrical parameter.

10. The method of claim 9 wherein the ending parameter is voltage.

11. The method of claim 9 wherein the ending parameter is current.

* * * * *

Exhibit-4

1:10-cv-11041-NMG

US005800460A

United States Patent [19]

Powers et al.

[11] **Patent Number: 5,800,460**

[45] **Date of Patent: Sep. 1, 1998**

[54] **METHOD FOR PERFORMING SELF-TEST IN A DEFIBRILLATOR**

[75] Inventors: **Daniel J. Powers**, Bainbridge Island; **David Cameron**; **Clinton S. Cole**, both of Seattle; **Thomas D. Lyster**; **Steven T. Mydynski**, both of Bothell; **Carlton B. Morgan**, Bainbridge Island, all of Wash.

[73] Assignee: **Heartstream, Inc.**, Seattle, Wash.

[21] Appl. No.: **834,346**

[22] Filed: **Apr. 16, 1997**

Related U.S. Application Data

[60] Continuation of Ser. No. 468,196, Jun. 6, 1995, abandoned, which is a division of Ser. No. 240,272, May 10, 1994, which is a continuation-in-part of Ser. No. 63,631, May 18, 1993, abandoned.

[51] **Int. Cl.**^{6} **A61N 1/39**

[52] **U.S. Cl.** **607/5**

[58] **Field of Search** 607/4–8; 364/481

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Primary Examiner—William E. Kamm

Attorney, Agent, or Firm—James R. Shay; Cecily Anne Snyder

[57] **ABSTRACT**

A defibrillator with an automatic self-test system that includes a test signal generator and a defibrillator status indicator. The test system preferably performs functional tests and calibration verification tests automatically in response to test signals generated periodically and/or in response to predetermined conditions or events and indicates the test results visually and audibly. The invention also relates to a method for automatically determining and indicating a defibrillator's status without human intervention.

7 Claims, 7 Drawing Sheets

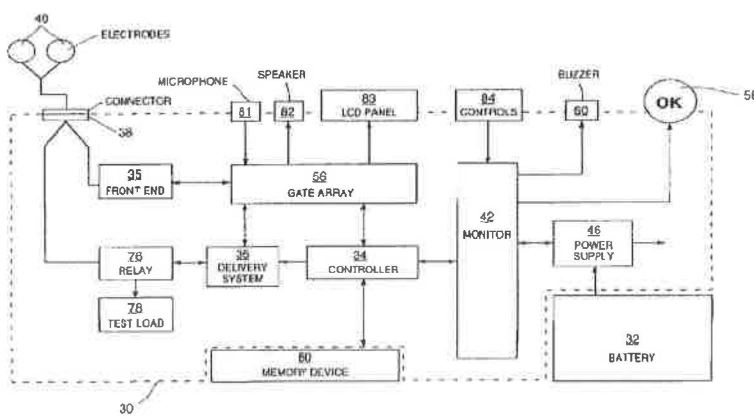

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Exhibit-4.00001

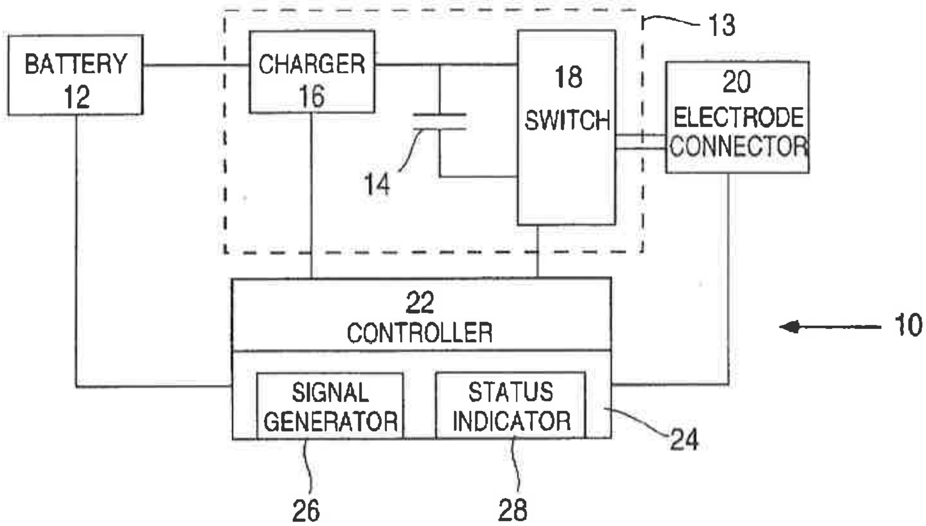
13
BATTERY
12
CHARGER
16
18
SWITCH
20
ELECTRODE
CONNECTOR
14
22
CONTROLLER
10
SIGNAL
GENERATOR
STATUS
INDICATOR
24
26
28

FIG. 1

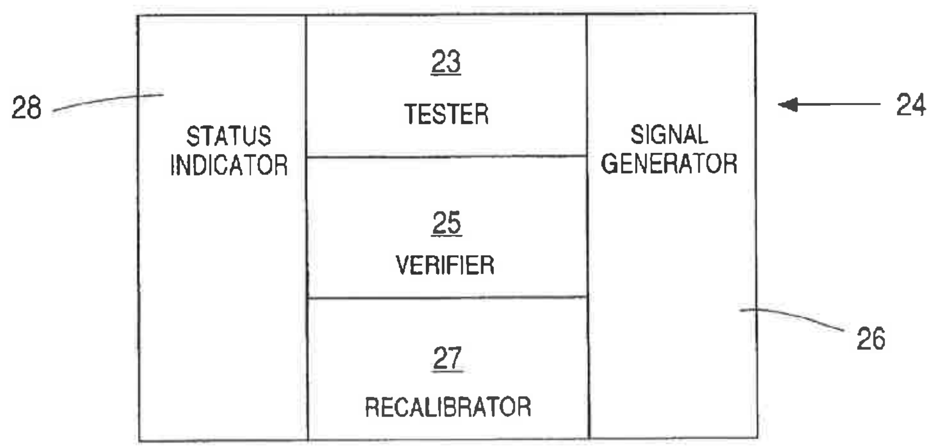
28
STATUS
INDICATOR
23
TESTER
25
VERIFIER
27
RECALIBRATOR
SIGNAL
GENERATOR
24
26

FIG. 2

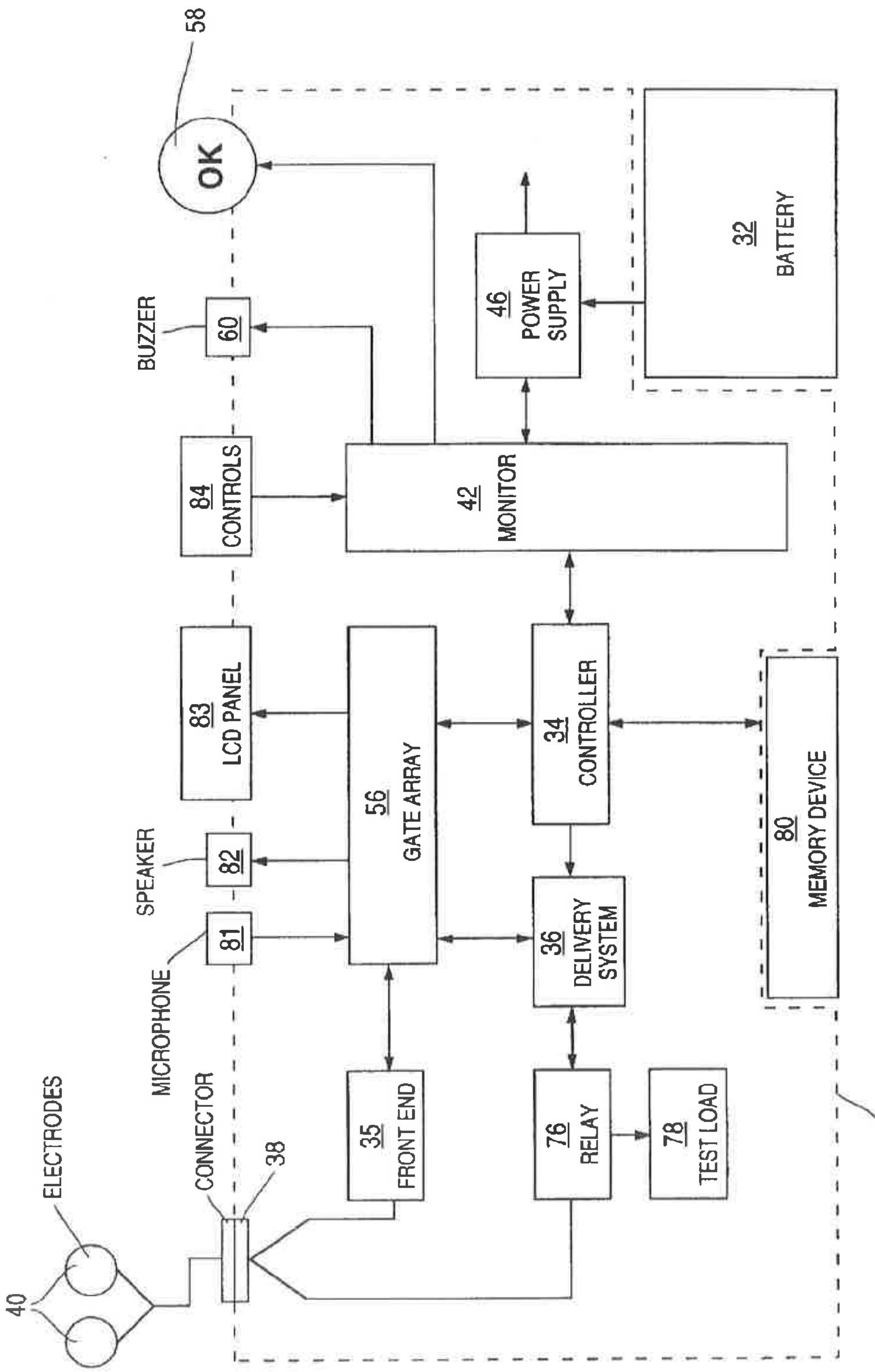
58
OK
BUZZER
60
84 CONTROLS
83 LCD PANEL
SPEAKER
82
MICROPHONE
81
ELECTRODES
40
CONNECTOR
38
46 POWER SUPPLY
32 BATTERY
42 MONITOR
56 GATE ARRAY
34 CONTROLLER
36 DELIVERY SYSTEM
35 FRONT END
76 RELAY
78 TEST LOAD
80 MEMORY DEVICE
30

FIG. 3

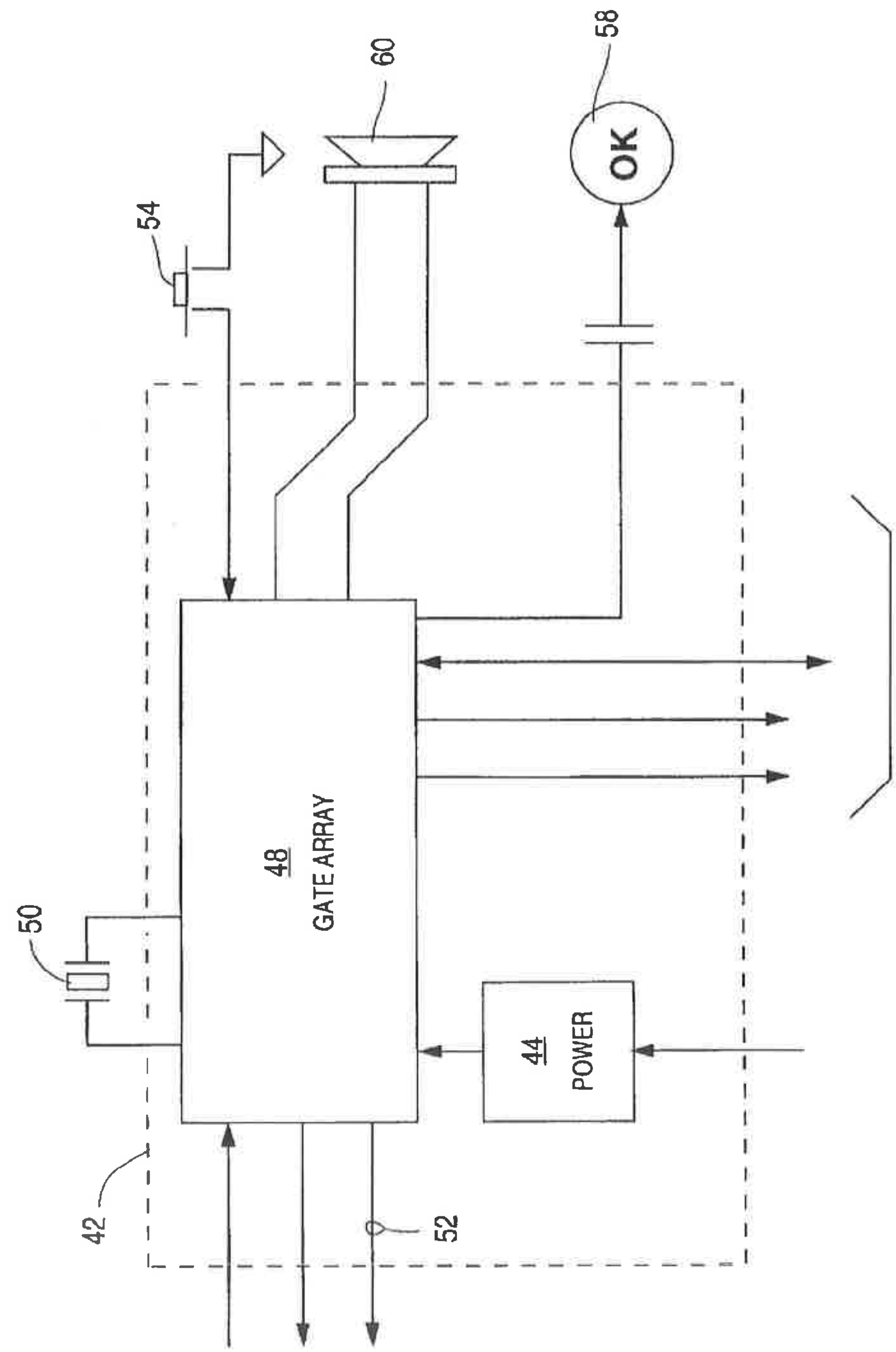

FIG. 4

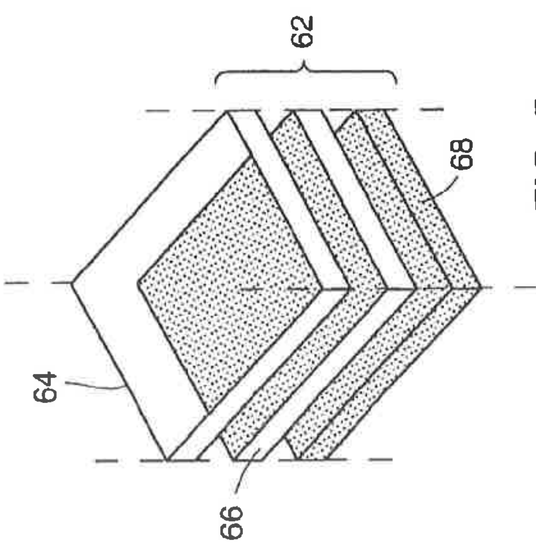

FIG. 5a

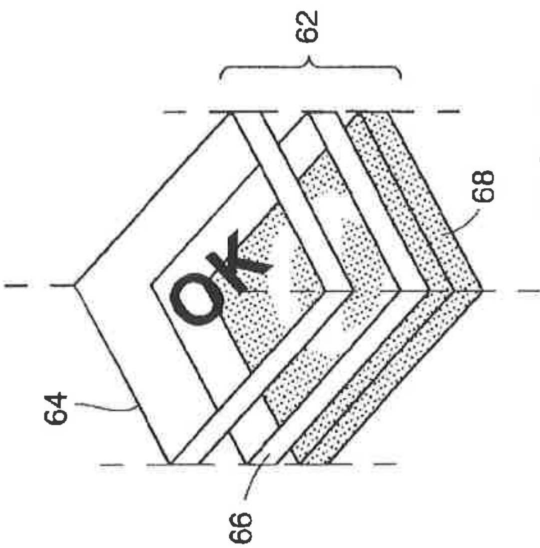

FIG. 5b

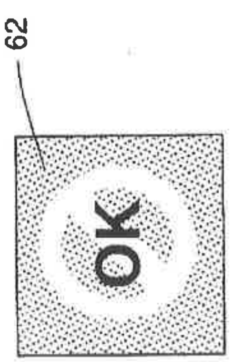

FIG. 5c

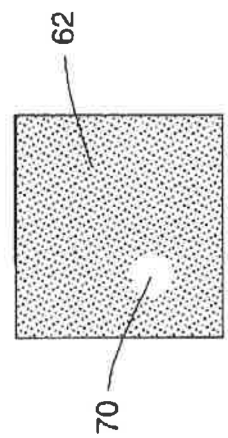

FIG. 5d

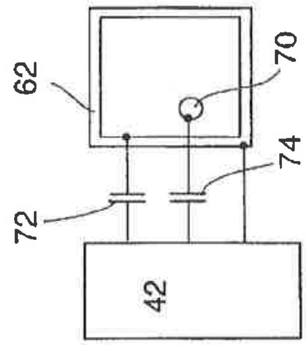

FIG. 5e

TEST DESCRIPTION	BIT	WPST	MPST	DPST	POST	RUN TIME
CPU SELF-TEST	X	X	X	X	X	
SYSTEM GATE ARRAY	X	X	X	X	X	
SYSTEM MONITOR GATE ARRAY	X	X	X	X	X	
PROGRAM ROM CRC	X	X	X	X	X	
SYSTEM RAM CHECKSUM	X	X	X	X	X	
VIDEO RAM CHECKSUM	X	X	X			
DEVICE FLASH ROM CHECKSUM	X	X	X			
SYSTEM WATCH DOG	X	X	X	X	X	X
PCMCIA CARD VERIFY	X					
FRONT END GAIN	X	X	X	X		
ARTIFACT SYSTEM	X	X	X	X		
CMR CHANNEL	X	X	X	X		
DEFIBRILLATOR CONN/RELAY	X	X	X	X		
BATTERY SENSE CELL MEASUREMENT						
BATTERY SENSE CELL LOAD MEASUREMENT	X	X	X	X	X	X
BATTERY STACK LOAD CHECK	X	X	X	X	X	X
POWER SUPPLIES CHECK	X	X	X	X	X	X
HV ISOLATION RELAY	X	X	X			
HIGH VOLTAGE DELIVERY SUBSYSTEM	X	X	X			
WAVEFORM DELIVERY						X
CALIBRATION STD. VOLTAGE	X	X	X	X	X	X
CALIBRATION STD. TIME	X	X	X	X	X	X
CALIBRATION STD. RESISTANCE	X	X	X			
STUCK BUTTON TEST	X	X	X	X		
BUTTON TEST	X					
LIGHT ALL LED'S	X				X	
LCD TEST PATTERN	X					
LCD BACKLIGHT VERIFY	X					
SPEAKER OUTPUT TEST	X				X	
PIEZO BEEPER TEST	X				X	

FIG. 6

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Exhibit-4.00006

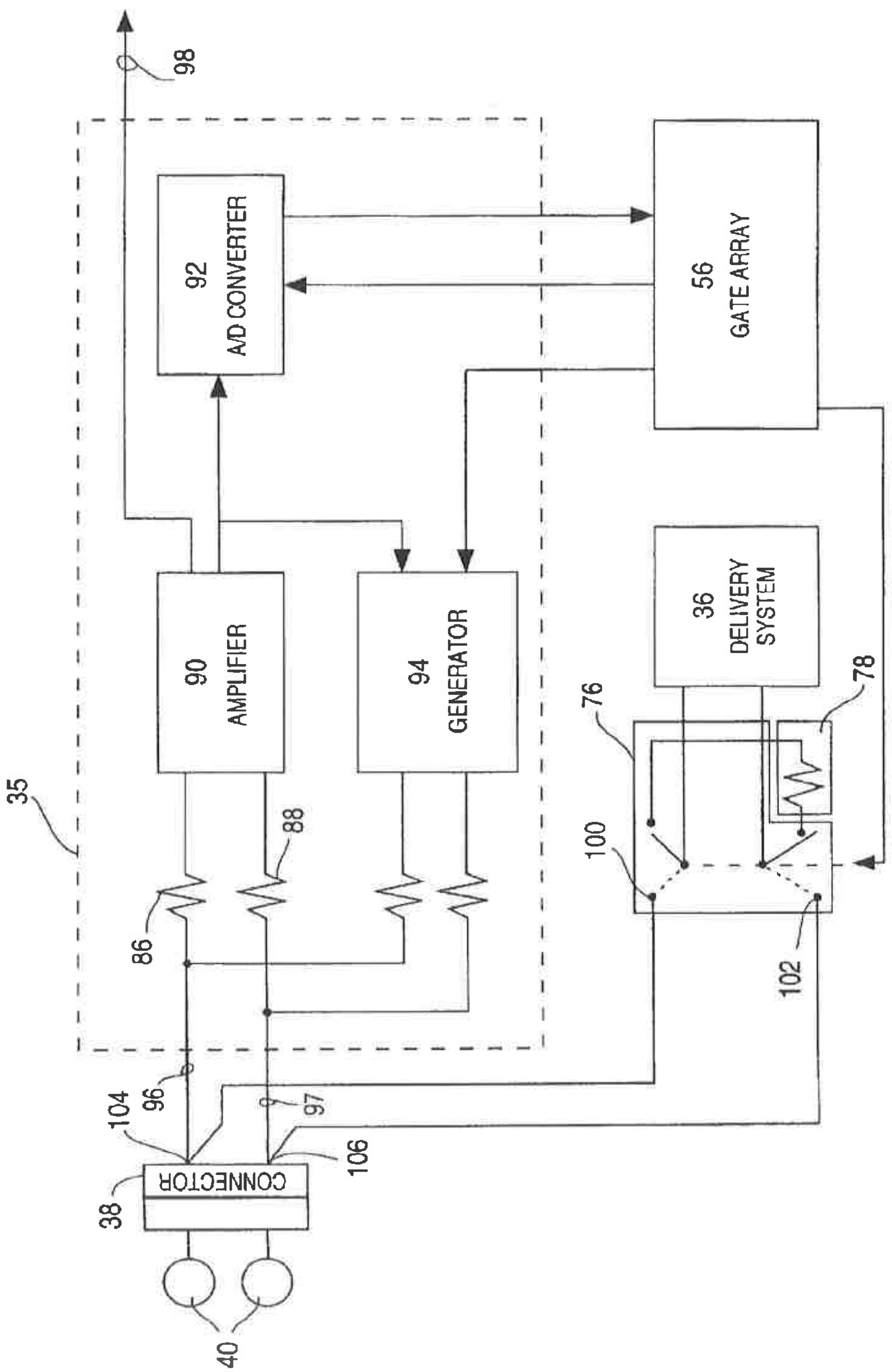
98
92
A/D CONVERTER
56
GATE ARRAY
90
AMPLIFIER
94
GENERATOR
36
DELIVERY
SYSTEM
35
88
86
76
78
100
102
104
96
97
106
CONNECTOR
38
40

FIG. 7

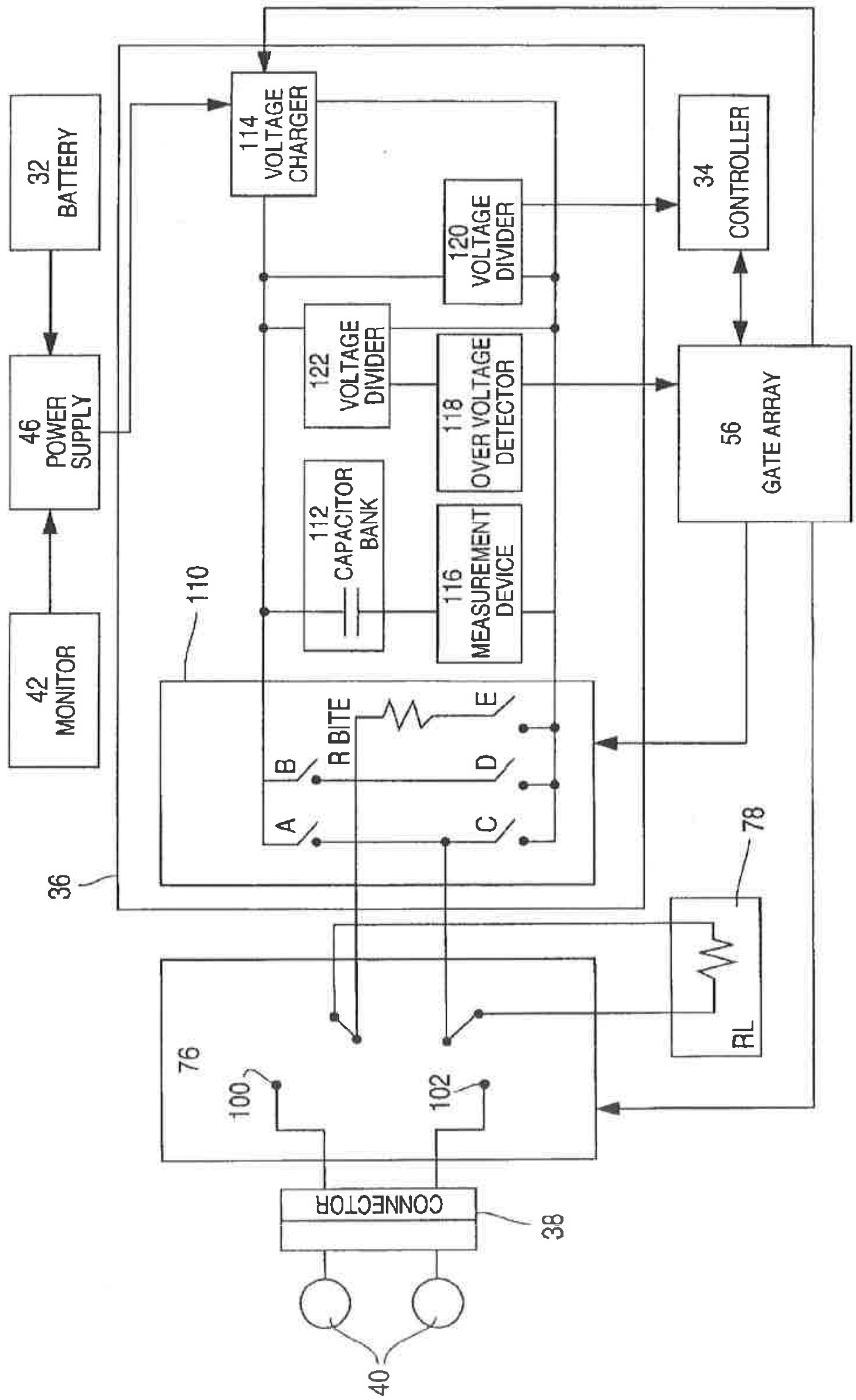
32 BATTERY
46 POWER SUPPLY
42 MONITOR
114 VOLTAGE CHARGER
120 VOLTAGE DIVIDER
122 VOLTAGE DIVIDER
118 OVER VOLTAGE DETECTOR
112 CAPACITOR BANK
116 MEASUREMENT DEVICE
34 CONTROLLER
56 GATE ARRAY
110
A
B
C
D
E
R BITE
36
78
RL
76
100
102
CONNECTOR
38
40

FIG. 8

METHOD FOR PERFORMING SELF-TEST IN A DEFIBRILLATOR

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 08/468,196, filed 6 Jun., 1995, now abandoned, which is a divisional of U.S. patent application Ser. No. 08/240,272, filed May 10, 1994, which is a continuation-in-part of U.S. patent application Ser. No. 08/063,631, filed May 18, 1993, and now abandoned the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to a defibrillator system that performs periodic self-tests and, in particular, to a method and apparatus for performing periodic functional, calibration and safety tests in an automatic external defibrillator to verify that the defibrillator's components and operation are within preset specifications.

Prior art external defibrillators were used primarily in the hospital. In that environment, the frequency with which a particular defibrillator was used was relatively high, e.g., on the order of several times per week. Periodic verification tests for these prior art defibrillators typically amounted to a battery level test and a functional test in which the defibrillator was hooked to a test load and discharged. These tests were usually performed once per day or once per shift per manufacturer recommendations. Other tests, such as recalibration of internal circuit components by a biomedical technician, were performed less often, on the order of twice per year, also pursuant to manufacturer recommendations. Each of these maintenance tests for prior art defibrillators was initiated and performed by human operators.

SUMMARY OF THE INVENTION

While adequate for relatively frequently-used hospital-based defibrillators, prior art defibrillator test apparatuses and procedures are not optimal for use with portable defibrillators that are used less frequently. For example, defibrillators carried by emergency medical vehicles might need to be used only on a monthly basis. The burden of performing manual battery and performance tests on a daily basis could outweigh the benefits of carrying the infrequently-used defibrillator on the vehicle. The tests should therefore be performed by the defibrillator automatically.

Because the tests are performed automatically, the tests should be both accurate and reliable. The portable defibrillator's mobile environment could add to the frequency of defibrillator component failure, thus increasing the need for periodic tests. In addition, portable defibrillators could be exposed to environmental conditions (such as severe vibration, sudden impacts, heat or moisture) that require an immediate reevaluation of a defibrillator's operational status.

Also, the nature of the tests performed should be different in the portable defibrillator environment because of the relatively infrequent use of the defibrillators. Deterioration of system components over time could move the defibrillator out of its originally specified operating parameters. An infrequently used defibrillator should provide an operator with an indication not only of whether it will operate at all but also verify that the defibrillator meets its established specifications.

Defibrillators are used in emergency situations in which time is of the essence. The operational status of a particular defibrillator as determined by the self-tests should be therefore readily apparent to an operator.

This invention is an external defibrillator that generates a test signal automatically in response to a predetermined schedule, in response to a predetermined event or condition, or periodically. The self-test system preferably turns on a power system within the external defibrillator in response to the test signal and performs a first test on a first periodic schedule and a second test on a second periodic schedule.

The invention is described in more detail below with respect to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram showing a defibrillator according to this invention.

FIG. 2 is a schematic diagram showing a testing system of a defibrillator according to this invention.

FIG. 3 is a block diagram showing some of the components of an external defibrillator according to a preferred embodiment of this invention.

FIG. 4 is a block diagram showing the system monitor of the embodiment of FIG. 3.

FIG. 5 parts (a)–(e) show various aspects of a visual display according to the embodiment of FIG. 3.

FIG. 6 is a table showing groupings of external defibrillator self-tests according to a preferred embodiment of this invention.

FIG. 7 is a block diagram showing the interaction of an ECG front end and a testing system according to a preferred embodiment of this invention.

FIG. 8 is a block diagram showing the interaction of a high voltage delivery system and a testing system according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

This invention is a method and apparatus for automatically determining the status of a defibrillator, for displaying that status to a user or operator, and, for recalibrating certain defibrillator components. The invention is particularly useful for increasing the reliability of infrequently-used defibrillators by providing an indication of a defibrillator's operational status and by recalibrating the defibrillator, where possible, prior to any attempted use of the defibrillator.

In a preferred embodiment, the defibrillator automatically generates a test signal either (1) periodically in response to the passage of time or (2) in response to a specified event or condition, such as the insertion of a new battery or a manual power-up command from an operator. The test signal initiates a plurality of preset self-tests within the defibrillator. The self-tests may include functional tests that verify the operation of certain defibrillator components and subsystems. The self-tests may also include calibration verification tests that determine whether certain defibrillator components and subsystems are operating at preset specifications or within preset specification ranges. In addition, the defibrillator may automatically recalibrate certain components or subsystems in response to a calibration verification test.

No matter what test or collection of automatic self-tests the defibrillator performs, the defibrillator indicates its

operational status as determined by the self-tests, such as through a visual display. The indication is preferably fail-safe so that a failure of the status indication mechanism itself will result in the indication of an inoperable defibrillator status.

FIG. 1 is a schematic representation of a defibrillator constructed and operated according to this invention. The defibrillator **10** includes a battery **12**, a high voltage delivery system **13** (preferably consisting of a capacitor or capacitor bank **14**, a capacitor charger **16** and a switching mechanism **18**), an electrode connector **20** and a controller **22** that operates the charger and switching mechanism to deliver an electric shock from the capacitor to electrodes connected to the electrode connector or interface **20**. The defibrillator has a testing system **24** including a test signal generator **26** and a defibrillator status indicator **28**. The purpose of testing system **24** is to test the operational status of the defibrillator's components and to provide an indication of that status automatically in response to predetermined events or conditions and/or periodically on a preset schedule.

While the testing system **24** and controller **22** are shown in FIG. **1** as separate elements, they could be combined into a single element that performs all testing and operational control functions. In addition, the testing system **24** may also include components located within other defibrillator subsystems, such as within the high voltage delivery system. In any event, the testing system communicates with the tested defibrillator components and systems via communication channels to control the tests and to gather information about the status of the tested components. The testing system also communicates indicator control signals to the status indicator via communication channels as well.

FIG. **2** is a schematic drawing showing self-testing subsystems making up testing system **24** in the preferred embodiment. It is not necessary that a given defibrillator include each of the subsystems shown in FIG. **2**. According to this invention, the defibrillator must include at least one automatic self-test that is initiated in response to a test signal generated either periodically or as a result of a specified event or condition.

Also, it is not necessary for the apparatus performing each test in each subsystem to be in the same physical location. FIG. **2** is a logical grouping and is not intended to be an actual drawing of a defibrillator or defibrillator subsystem.

Each self-test in each group of FIG. **2** responds to a test initiation signal from signal generator **26**, and the result of each self-test in each group affects the status is indicated on status indicator **28**. This collection of self-testing subsystems may be added to or subtracted from without departing from the invention. In addition, while there may be other tests performed by the defibrillator that do not meet these criteria, such tests form no part of this invention.

The first testing subsystem is the functionality tester **23**. The self-tests performed by this subsystem test the operability and functionality of defibrillator components and/or subsystems. Examples include the testing of switches within the switching mechanism of the high voltage delivery system and the testing of registers within the defibrillator's controller.

The second testing subsystem is the calibration verifier **25**. The self-tests performed by this subsystem determine whether certain defibrillator components and/or subsystems meet preset specifications. Examples include determining the capacitance of the defibrillator's capacitor and checking the response of the controller to capacitor voltage values.

The testing system also may include a recalibrator **27** that adjusts a component or subsystem of the defibrillator in response to a determination that the component or subsystem is no longer, or no longer operates, at a specified value or within a specified range of values. For example, parameters used by the defibrillator's controller to control operation of the high voltage delivery system may be changed to reflect changes in the values of defibrillator components.

The actual self-tests automatically performed by a defibrillator's testing system depend in part on the defibrillator's structure and in part on reliability goals set by the defibrillator's designer. Trade-offs may be made between the completeness of a given self-test (which adds to the reliability of the defibrillator product) and the cost of implementing a complete and accurate self-test. A particular implementation of a defibrillator and its self-testing system is described below. The discussion merely illustrates a preferred embodiment of the invention. Our invention covers other defibrillator designs and other collections of external defibrillator self-tests as well.

FIG. **3** is a block diagram showing a preferred configuration for the defibrillator of this invention. Some of the elements are described in more detail further below. Defibrillator elements not specifically described in this application may be configured and operated in the manner described in U.S. patent application Ser. No. 08/227,553, "Electrotherapy Method and Apparatus," filed Apr. 14, 1994, the disclosure of which is incorporated herein by reference.

As shown in FIG. **3**, defibrillator **30** has a power source such as a removable battery **32**, a controller such as CPU **34**, and a high voltage delivery system **36** including a capacitor or capacitor bank and appropriate switches (not shown) to deliver a pulse of electrical energy to an electrode connector or interface **38** and then to a patient via electrodes **40**. Delivery of the electrical pulse is controlled by CPU **34**. A test and isolation relay **76** and a test load **78** are provided for reasons explained below.

An ECG front end system **35** acquires and preprocesses the patient's ECG signals through electrodes **40** and sends the signals to CPU **34** via a system gate array **56**. System gate array **56** is a custom application specific integrated circuit (ASIC) that integrates many of the defibrillator's functions, such as display control and many of the instrument control functions, thereby minimizing the number of parts and freeing up main CPU time for use in other tasks. The system gate array could be replaced by discrete logic and/or another CPU, of course, as known in the art.

The external defibrillator shown in FIG. **3** also has a memory device **80** (such as a removable PCMCIA card or a magnetic tape), a microphone **81**, a speaker **82**, a LCD panel **83** and a set of illuminated push-button controls **84**. None of these elements is critical to the present invention.

A system monitor mediates the external defibrillator's self-testing functions by watching for scheduled test times and unscheduled power-on events. The system monitor generates test signals periodically at scheduled times and in response to specified events. The system monitor is also responsible for operating a fail-safe defibrillator status indicator or display. The system monitor communicates test signals to the CPU via a communication channel, and the CPU controls and gathers information from tested defibrillator components via other communication channels, some of which pass through system gate array **56**.

In the embodiment shown in FIG. **3**, system monitor **42** is separate from CPU **34** so that power can be provided to the system monitor without powering any other part of the defibrillator. Thus, system monitor **42** has its own power

supply **44** apart from the defibrillator power supply **46**, as shown more specifically in FIG. **4**. This dedicated power supply **44** draws approximately **30** microamps from battery **32** and is active whenever power is available from the battery. The dedicated system monitor power supply may also have its own battery apart from the main battery.

As shown in more detail in FIG. **4**, the other major element of system monitor **42** is a low-power gate array **48**. In this preferred implementation, gate array **48** is a 44-pin custom ASIC. Gate array **48** is preprogrammed to perform the functions of the system monitor. As an alternative, the system monitor could be implemented with a low power CPU and/or with discrete logic components.

Gate array **48** operates a 32.768 kHz crystal oscillator to provide the defibrillator testing system's scheduling function. The gate array divides the oscillator's frequency repeatedly to generate periodic (e.g., daily, weekly, monthly) test initiation signals. The system monitor also sends a 32.768 kHz clock signal out on line **52** to be used by the defibrillator system to perform other functions.

In addition to the periodic tests, certain defibrillator self-tests are performed rapidly in response to activation of the defibrillator's ON button (shown schematically as element **54** in FIG. **4**) by an operator. Activation of the ON button **54** prompts the system monitor to generate a power-on test initiation signal.

The system monitor indicates the status of the defibrillator as a result of the periodic and power-on self-tests. The status indicator should be fail-safe so that the indicator will indicate an inoperable status if the system monitor should fail. The system monitor communicates control information to the status indicator through communication channels.

In a preferred embodiment, the system monitor **42** powers a status indicator consisting of a visual display **58** and a piezo buzzer **60** to indicate the operational status of the defibrillator to a user. As shown in more detail in FIG. **5**, visual display **58** may be a multiple-part LCD **62** powered by the system monitor via AC-coupled drive **72**. The top plate **64** of the LCD is a clear window with an "OK" symbol printed on its back. The middle plate **66** is an LCD shutter that is biased so as to be opaque when driven by the system monitor via drive **72**. The bottom plate **68** has an international "Not" symbol on its top surface. Middle plate **66** also includes a separately addressable portion **70** driven by the system monitor via AC-coupled drive **74**.

In operation, the system monitor **42** drives LCD shutter **66** only when confirmation of successful testing is received within an expected time window. The visual display would then appear as in FIG. **5**(*d*). Failure to receive proper test confirmation within the allotted time window will cause the system monitor to cease issuing drive signals to shutter **66**. Shutter **66** will then go transparent to superimpose an international "Not" symbol on the "OK" symbol in the LCD as shown in FIG. **5**(*c*). The system monitor will also then begin powering a piezoelectric failure alert buzzer **60**, preferably for 200 msec. every **10** sec. so long as there is power enough to do so.

The primary advantages of the visual display of the preferred embodiment are its low power requirements and the fact that it is powered by an AC signal rather than a DC signal. This latter point ensures the display's fail-safe nature, since the shutter of middle plate **66** cannot be maintained opaque without the active involvement of the system monitor generating the AC signal.

Separately addressable portion **70** serves as a positive indication (in addition to the fail-safe "OK" symbol) that the defibrillator has power and is functioning properly. Portion **70** blinks periodically through the alternating driving and releasing of the signal to portion **70** through drive **74**.

In an alternative embodiment, an LCD shutter covering an "OK" symbol is driven open to display the "OK" symbol to indicate an operational defibrillator status. The shutter is permitted to close to cover the "OK" symbol to indicate that the defibrillator is not operational. Another alternative category of fail-safe indicators include electromechanical devices, such as those used for aircraft instrumentation.

In response to the generation of a test initiation signal, the system monitor commands the defibrillator's power system to turn on. The CPU then issues an appropriate series of commands to perform the required tests. The tests performed in response to the periodic and power-on test initiation signals are described in more detail further below with reference to the table shown in FIG. **6**.

FIG. **6** shows the scheduling of some of the tests that can be performed by the self-test system of this invention. Some of the tests are performed when a battery is inserted, some are performed daily, some are performed weekly, some are performed monthly, some are performed when an operator powers-up the external defibrillator, and some are performed during operation of the defibrillator. FIG. **6** is not an exhaustive list of possible tests, nor is performance of any particular test listed in FIG. **6** essential to the invention. The tests and test groupings shown in FIG. **6** are merely an example illustrating this invention.

The first test grouping is the Battery Insertion Test or BIT. The BIT tests all internal subsystems, allows the user to verify PCMCIA card type, setup parameters, and the proper operation of systems that are only externally observable (e.g., LCD operation and button functionality). The BIT is performed whenever a good battery is inserted into the defibrillator, unless the defibrillator's electrodes are attached to a patient.

The second test grouping shown in FIG. **6** is the Monthly Periodic Self-Test (MPST). The MPST performs the same automated tests as the BIT, but in order to conserve power it does not run the externally observable systems (e.g., LCD, LED's, etc.). The MPST is performed once every 28 days so long as a good battery is maintained in the defibrillator.

The third test grouping shown in FIG. **6** is the Weekly Periodic Self-Test (WPST). The WPST performs essentially the same automated tests as the MPST, except the test shock is not performed in order to conserve power. The WPST is performed once every 7 days so long as a good battery is maintained in the defibrillator.

The fourth test grouping shown in FIG. **6** is the Daily Periodic Self-Test (DPST). The DPST performs fewer tests than the WPST in order to conserve power.

The fifth test grouping shown in FIG. **6** is the Power-On Self-Test (POST). The POST is performed whenever an operator turns the defibrillator from OFF to ON in preparation for use of the defibrillator on a patient. The tests performed in the POST are selected to provide the highest confidence of instrument functionality in the shortest possible time.

The final grouping of tests in FIG. **6** is the Runtime Tests. These tests are performed continually during runtime to assess the safety and effectiveness of portions of the defibrillator. The tests are explained in more detail below.

The self-tests listed in FIG. **6** are not necessarily listed in the order performed. The performance order depends in part on the interrelationship of the components and functions

tested. To the extent there is no such relationship, then the self-test order is arbitrary.

In general, failure of a self-test results in an indication of an inoperable status or error status by the defibrillator's status indicator. For example, in the defibrillator described above, failure of a self-test would result in the display of the "Not OK" symbol by the system monitor and activation of the audible failure signal. The system monitor takes this action if it receives a signal from the CPU or from the system gate array that a test has failed (i.e., that a tested component is not functional or that the component's calibration could not be verified) or if the system monitor does not receive information showing that the currently-scheduled self-test has passed before the expiration of the watchdog's time-out period (e.g., 200 msec.).

In a preferred embodiment of this invention, self-test scheduling and result information may be stored in system memory for later diagnosis of the defibrillator by a technician or operator. For example, in the defibrillator described above, date and time information regarding the self-tests performed are stored in internal memory and/or in the removable memory 80 (e.g., PCMCIA card) so that a history of performed tests can be obtained by a technician or operator. In addition, if a self-test indicates that a component or subsystem is not functional or is out of calibration, or if any recalibration has been performed, detailed information about that test is stored in internal memory and/or in removable memory. Information regarding environmental conditions (temperature, humidity, moisture, impacts) may also be stored for use in later diagnosis.

The CPU self-test is a functional test. During the CPU self-test the CPU tests its internal register integrity and verifies its access to local and external memory locations. If the CPU does not pass these initial tests, it attempts to notify the user of a system failure by writing to a system failure register in the system monitor, resulting in a status display showing "Not OK". If the CPU does not respond to the system monitor within 200 msec of power on, the system monitor assumes the CPU is dead, and the "Not OK" symbol is displayed.

The System Gate Array self-test is also a functional test. In the System Gate Array self-test, the CPU verifies that it can write to and read from the system gate array register set. This test also tests other components of the system gate array, such as whether defibrillator waveform control state machines are functioning correctly. Test failures are handled as for the CPU self-test above.

The System Monitor Gate Array self-test is a functional test as well. The System Monitor Gate Array self-test verifies that the CPU can write to and read from the system monitor.

At the beginning of the Program ROM CRC (Cyclic Redundancy Check) self-test, the CPU resets the system monitor watchdog and executes a CRC on program ROM. This test is a functional test.

In the System RAM Checksum self-test (a functional test), RAM used for data memory is verified using a test pattern that has a high probability of identifying both address and data faults within RAM. Once the pattern has been written to system RAM, the test calculates a checksum based on the system RAM contents.

In the Video RAM Checksum self-test, RAM used for video memory is verified in the same-manner as for the system RAM. This self-test is a functional test.

In the Device Flash ROM Checksum self-test, a checksum of the voice data pointer and voice data record is calculated and compared with the checksum value stored in the internal flash ROM. This self-test is a functional test as well.

In the System Watchdog Verify self-test, the CPU verifies the watchdog by writing a known watchdog time-out into the watchdog register and looping until the watchdog time-out register in the system monitor indicates that the watchdog timer has expired. During this test, the watchdog outputs, NMI, and RESET are disabled. The CPU signals a failure if the watchdog timer does not expire within the expected time frame.

The PCMCIA Card Verify self-test is a functional test that checks for the presence and type of the removable memory.

The next four self-tests listed in FIG. 6—Front End Gain, Artifact System, CMR Channel, and Defibrillator Connector/Relay—are all part of the ECG front end tests. These tests verify the functionality and verify the calibration of the ECG input circuitry and the patient/electrode connection circuitry. These tests are not performed during the POST since the tests assume that there is no load attached to the defibrillator output connector.

An explanation of some special features of the external defibrillator of this invention is required as background for the ECG front end tests. FIG. 7 shows the ECG front end 35 in relationship to the system gate array 56, the high voltage delivery system 36, a test and isolation relay 76 and the patient connector 38, as well as communication channels among some of these elements. The test and isolation relay 76 is normally in the state shown in FIG. 7 so that no shock can be delivered from the high voltage delivery system 36 to the patient connector 38 and to the electrodes 40 attached to a patient.

In this state, any signals from electrodes 40 will pass through a pair of protective resistors 86 and 88 to an ECG amplifier 90. A high resolution A/D convertor 92 digitizes the ECG data and sends it to the system gate array 56 for processing by the CPU to determine whether a shock is required. The system gate array 56 also sends control signals to the A/D convertor 92.

The ECG front end 35 also has a patient/electrode connection tester consisting of a signal generator 94 connected to the ECG signal input lines through a pair of protection resistors. The signal generator 94 receives input from the ECG analog output and carrier frequency commands from the gate array. The patient/electrode connection tester also produces an artifact test signal which is sent through ECG amplifier 90 to the CPU via line 98. ECG signal collection and analysis and artifact detection are not part of the present invention.

During automated testing, the system gate array 56 uses the signal generator 94 as a test signal injector to verify the function of the various ECG front end elements, wiring to the patient connector 38, and the normally-open contacts of the test and isolation relay 76. To test the ECG processing elements, the system gate array 56 causes the signal generator 94 to inject a small, low-frequency signal mimicking the amplitude and frequency characteristics of an ECG signal, thereby simulating a patient being monitored by the defibrillator. As the frequency of this test signal is varied, the digital data stream from the system gate array is checked by the CPU for values indicative of proper gain and filtering characteristics of the ECG front end, thus verifying the functionality and calibration of the analog and A/D conversion pathways.

In the Defibrillator Connector/Relay self-test, the function of the test and isolation relay contacts 100 and 102 and

patient connector wiring are tested. The system gate array **56** causes the signal generator **94** to emit a 100 microamp, 600 Hz test signal and concurrently switches the test and isolation relay **76** to the normally-open position (shown in phantom in FIG. **7**). The test current signal is carried to a 4-wire connection **104** and **106** directly on the patient connector contacts, through the relay common connection, and into the high voltage delivery subsystem **36**, where both signal lines are held at ground potential. The relay **76** is then switched to its normally closed position. Carrier voltage is measured in both positions is indicative of the resistance of the circuit tested. When the relay is in normally open position, the carrier voltage should be approximately equal to the full scale voltage of signal generator **94**. When the relay is in the normally closed position, carrier voltage should be approximately zero.

Finally, in the Artifact System self-test, the system gate array causes the signal generator **94** to emit signals indicative of artifact generation at the electrodes. Proper receipt of artifact signals of the expected amplitude at the CPU verifies the function and calibration of this channel.

There are three battery-related self-tests that are members of each of the test groupings in the preferred embodiment. The battery tests described below are based on a defibrillator design using the battery capacity indicator described in U.S. patent application Ser. No. 08/182,605, filed Jan. 14, 1994, now U.S. Pat. No. 5,483,165, (specifically, the embodiment of FIG. **2**) the disclosure of which application is incorporated herein by reference. Other battery charge sensor arrangements and other battery charge subsystem self-tests may be used, of course, without departing from the scope of the invention.

The Battery Sense Cell Measurement self-test listed in FIG. **6** refers to a battery capacity test described in Ser. No. 08/182,605 in which a parameter of a single battery cell is monitored to determine the remaining capacity of the entire battery. In the preferred defibrillator configuration, this functional self-test determines whether the remaining battery capacity is sufficient for performing one more use of the defibrillator by determining whether the voltage of the sense battery cell is above a threshold value of approximately 2 volts. If not, then a Low Battery Warning State is entered. If this state is entered during a BIT, DPST, WPST or MPST, the unit returns to Stand-by mode displaying the "Not OK" symbol. If this state is entered during a POST or during runtime, the user is alerted by a symbol appearing on the LCD display **83** and with an audible prompt.

The second listed battery self-test is the Battery Sense Cell Load Check. This calibration verification self-test verifies the sense cell additional load circuitry described in Ser. No. 08/182,605 by turning the additional load circuitry on and off and measuring the voltage load across the load resistor. This test can actually be performed while performing the first battery self-test.

The third listed battery self-test is the Battery Stack Check. This functional test measures the voltage of the entire battery cell stack as a cross-check against the Battery Sense Cell Measurement test. If a portion of the battery stack other than the sense cell has been damaged, the voltage of the entire stack could be different than that which would have been expected based on the sense cell test.

In the Power Supplies Check calibration verification self-test, the system monitor activates the defibrillator's power supply system to supply power to all of the instrument's elements. Scaled representations of the voltages from the supplies are input for verification to the main CPU A/D

convertor. For example, the major power supplies are: +18 volt switched battery; +5 volt for system monitor; +5 volts for main logic and analog; −5 volt for analog only; −14 to −22 volt CPU adjustable for LCD bias; +20 volts for IGBT switch drives; +2.5 volt reference for ECG front end; +5 volt reference for main CPU A/D convertor; and 50 ma current source supply for LCD backlight (tested by voltage developed). In addition, the high voltage supply is tested by its ability to charge the capacitor.

The HV Isolation Relay self-test determines the functionality of the test and isolation relay **76**. In the first part of the test, the system gate array **56** moves the test and isolation relay to its normally open position, i.e., with the switches against contacts **100** and **102**. The ECG front end measures the impedance across conductors **96** and **97**. If the measured impedance corresponds to a predetermined impedance value, then the relay passes this part of the test.

The ECG front end then measures the impedance across conductors **96** and **97** with the test and isolation relay **76** in the normally closed position shown in FIG. **7**. The measured impedance should be high (>14k Ohms). If not, either a load is present at electrodes **40** or the relay failed to move completely to the normally closed position. In either case, the test fails, and the system monitor displays the "Not OK" symbol on the status indicator. In addition, failure to meet both parts of the Isolation Relay test prevents the defibrillator from performing the High Voltage Discharge Test described below.

Under normal conditions, the defibrillator used to implement and practice the preferred embodiment of this invention delivers a biphasic waveform to the patient, as described in more detail in U.S. patent application Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454. FIG. **8** provides further information regarding the preferred defibrillator's high voltage delivery system and how its operation is verified and calibrated during self-test.

High voltage delivery system **36** has a capacitor or capacitor bank **112** which can be charged to a preset voltage through a high voltage charger **114** connected to the power supply system **46** and battery **32**. Operation of the high voltage charger is controlled by system gate array **56**. A high voltage switch **110** consisting of five switches A–E and a shunt resistor R_{BITE} controls delivery of the biphasic waveform from capacitor **112** to the patient connector **38** through test and isolation relay **76** under the control of system gate array **56**.

Information regarding charge, current and voltage parameters at the capacitor is provided to system gate array **56** by a current and charge measurement device **116**, an overvoltage detector **118** and a voltage divider **120**. As described in more detail in Ser. No. 08/227,553, current and charge measurement device **116** is preferably a comparator that trips when a preset charge amount has been transferred from capacitor **112**. The time required for this charge transfer is determined by system gate array **56** and is used to determine first and second phase durations via a look-up table in system gate array **56**. All information and control signals pass among the elements via communication channels, some of which are shown schematically in FIG. **8**.

As explained in Ser. No. 08/227,553, resistor R_{BITE} is part of an overcurrent protection mechanism to protect circuit components from the effects of high current in the event that the impedance load between electrodes **40** is too low. Unless the initial current as measured by current and charge measurement device **116** is below a preset threshold, R_{BITE} is kept in the waveform delivery circuit to limit the current flowing from capacitor **112** through the switching mechanism **110**.

The high voltage delivery system has an overvoltage protector that protects switching circuit components from the effects of excessive voltage in the event of a higher than expected patient load resistance by preventing any transition from a first biphasic waveform phase to a second biphasic waveform phase. Analog voltage information from the capacitor is fed from a voltage divider **122** to an overvoltage detector **118**. Overvoltage detector **118** is preferably a comparator that trips at a preset voltage. The status of the comparator is communicated to system gate array **56**, which controls operation of the switching mechanism **110**.

Finally, analog information regarding the charge state of capacitor **112** is sent to CPU **34** via voltage divider **120**, where it is converted to digital form. This capacitor voltage information is used by the CPU to control capacitor charging.

The High Voltage Delivery Subsystem self-test actually includes a number of individual self-tests. Capacitor **112** is charged to full voltage (e.g., approx. 1710 volts). As the capacitor voltage rises, the calibration of the overvoltage detector **118** is checked to see that it trips at the proper threshold voltage. If it fails to trip, the system gate array returns a signal to the system monitor to show "Not OK" on the status indicator.

After the capacitor has been fully charged, the system gate array **56** sets the high voltage switch **110** to its normal initial discharge position (switches A and E closed, all other switches open) and commences discharge of the capacitor through the test and isolation relay **76** to the test load resistance R_L. R_L simulates the load of a patient to whom the defibrillators electrodes may be attached. R_L is preferably approximately 10 ohms, however, which is smaller than the minimum allowable patient resistance for the defibrillator. This low resistance assures that the test stresses all of the elements tested in the high current pathways for worst-case patient conditions.

During this part of the High Voltage Delivery self-test, the system gate array verifies overcurrent detection calibration by determining whether the CPU correctly identifies the overcurrent condition detected by current and charge measurement device **116**. The system gate array also checks for proper operation of the charge threshold detector and that the overvoltage detector **118** trips properly when the capacitor voltage drops below the safe voltage threshold, in both cases by determining whether these events occur at their expected times. If either of these parameters is not its expected value, the system monitor displays "Not OK" on the status indicator.

As the capacitor voltage drops during discharge through the test load, the current measured by the current and charge measurement device **116** drops as well. The CPU marks the time the current drops below the overcurrent threshold (t_0). As the current continues to fall, the CPU marks the time (t_1) that the current reaches a value that is 37% of the overcurrent threshold. The difference of these two times is the time constant given by the product of the capacitor value C and the series resistance:

$$t_1-t_0=(R_L+R_{BITE})*C.$$

Switch D is then closed to short out R_{BITE}. This results in another overcurrent situation, and the CPU once again marks the time (t_2) of capacitor decay to the overcurrent threshold and the time (t_3) to 37% of the threshold. Since R_{BITE} has been removed,

$$t_3-t_2=R_L*C.$$

Since the time measurements can be made very accurately, the relationships between the resistive and capacitive components (and therefore their calibration) can be verified very accurately as well:

$$\frac{t_1-t_0}{t_3-t_2}=\frac{R_L+R_{BITE}}{R_L}$$

$$C=\frac{t_3-t_2}{R_L}$$

If the calculated resistance value differs from the expected value by more than a predetermined amount (e.g., 1%), or if the calculated capacitance value differs from the expected value by more than a predetermined amount (e.g., 5%), the system monitor displays the "Not OK" symbol.

In the preferred embodiment, the gain of the comparators of the current and charge measurement subsystems are determined by the particular values of the components used during assembly of the device. Due to allowable tolerance variation of the components, the times that the currents pass associated threshold values (t_0 and t_2) may vary from ideal values (t_0(ideal) and t_2(ideal)). Actual values of t_0 and t_2 are measured during self-test of the instrument and compared to stored t_0(ideal) and t_2(ideal). If the actual values of t_0 and t_2 measured during the High Voltage Discharge Test differ from the ideal values by less than a preset amount, then the gain on the comparator of the current and charge measurement device **116** is automatically recalibrated by the CPU to a range closer to the ideal value. If the actual values differ from the ideal by the preset amount or more, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

In a similar manner, the expected time for times for the measured charge delivery to cross the charge threshold used to determine first and second phase durations in normal operation is compared to the actual time. If the difference is less than a preset value, the CPU recalibrates the phase durations by recalculating the phase duration values according to a predetermined equation and storing the new values in the look-up table. Alternatively, the CPU could simply replace the original look-up table with another that is correlated with a particular time difference. If the time difference is equal to or greater than the preset value, then the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

Another feature of the external defibrillator of preferred embodiment is an undercurrent detector. If the patient to whom the electrodes are attached has an impedance greater than a specified value, or if one of the electrodes has become dislodged or unattached, in normal operation the defibrillator's discharge will abort. This condition is detected by the current and charge measurement device **116** in conjunction with the CPU.

The High Voltage Delivery self-test verifies calibration of the undercurrent detector by determining whether the low current condition is detected as the capacitor continues its discharge and the discharge current falls. If the CPU fails to detect the undercurrent condition, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

After the capacitor has completely discharged, it is recharged and discharged through the second current path by opening all switches in high voltage switch **110**, then closing switches B and C. Many of the same parameters described above can be measured to verify the functionality of switches B and C.

The Waveform Delivery self-test is performed only while the defibrillator is operating in normal mode (e.g., connected

to a patient). The defibrillator evaluates the measured and calculated waveform parameters after each delivered shock to determine if the waveform was delivered as expected. For example, if the defibrillator is constructed and operated according to U.S. patent application Ser. No. 08/227,553, the defibrillator will analyze waveform parameters such as start voltage, phase 2 end voltage, phase 1 duration and phase 2 duration. If the delivered waveform parameters cannot be reconciled with other information available to the defibrillator, the defibrillator warns the operator of a potential fault condition by, e.g., displaying a warning on the defibrillator's LCD.

The three Calibration Standard self-tests are an automatic way of verifying that defibrillator system standards have not drifted out of calibration. The standards are the values of R_L, R_{BITE}, the system monitor clock, the CPU clock, the CPU A/D convertor reference voltage and the ECG front end A/D convertor reference voltage. For all test groupings except the run time test, the voltage references are checked against each other to determine if either has drifted far enough from its expected value to affect the accuracy of the defibrillator. Specifically, the analog reference voltage for the ECG front end A/D convertor (which has an expected value of 2.5 volts in the preferred embodiment) is measured by the CPU A/D convertor. If the measured digital value differs from 2.5 volts by more than a predetermined tolerance, then at least one of the two reference voltages (i.e., either the ECG front end A/D convertor reference voltage or the CPU A/D convertor reference voltage) has drifted so far so as to affect the reliability of the device.

The time references are cross-checked in a similar way. The CPU counts the clock pulses from the system monitor clock for a predetermined amount of time (as measured by the CPU clock). If the number of counted system monitor clock pulses differs from its expected value by more than a predetermined amount, then at least one of the two clocks has drifted out of the tolerance range.

In addition, as discussed above, the High Voltage Delivery self-test cross-checks the values of R_L and R_{BITE}. Verification of the calibration of all three sets of reference variables is a prerequisite to the overcurrent detection calibration and charge threshold detection calibration described above.

In normal stand-by mode, the contacts beneath all buttons should be open. The Stuck Button self-test determines whether any of the contacts are closed. If so, the test returns a "Not OK" signal.

The remaining tests require user intervention and/or observation and are therefore part of only the BIT or POST test groupings. In the Button test, the user is prompted to depress identified buttons on the instrument to determine whether the buttons are functioning properly. All of the other tests run without user intervention. They each require the user to observe that the defibrillator elements tested are functioning correctly.

In addition to performing the self-tests according to the periodic schedule and in response to the battery insertion and operation of the defibrillator (as shown in FIG. 6), a group of self-tests can be performed automatically in response to environmental events, such as mechanical shock, e.g. as in a fall (as measured by an accelerometer); vibration (also as measured by an accelerometer); the invasion of moisture into the defibrillator housing (as measured by a humidity sensor); or exposure of the defibrillator to temperature extremes (as measured by a thermocouple, thermistor or other temperature sensor).

Variations of the structure and methods described above are within the scope of this invention. Tests and test structures may be tailored to meet the needs of a particular defibrillator design and its intended use environment.

What is claimed is:

1. A method of performing a self-test in an external defibrillator, the method comprising the following steps:

generating a test signal automatically;

turning on a power system within the external defibrillator in response to the test signal; and

performing a plurality of automatic self-tests within the external defibrillator for determining the status of the defibrillator.

2. The method of claim 1 wherein the turning on step comprises providing power to a central processing unit to perform the self-tests.

3. The method of claim 1 wherein the generating step comprises generating a test signal automatically upon a predetermined event or condition.

4. The method of claim 1 wherein the generating step comprises generating a test signal periodically.

5. The method of claim 1 wherein the performing step comprises performing said plurality of automatic self-tests within the external defibrillator on a schedule.

6. The method of claim 5 wherein the performing step comprises performing a first automatic self-test on a first periodic schedule.

7. The method of claim 6 wherein the performing step comprises performing a second automatic self-test on a second periodic schedule.

* * * * *

Exhibit-6

1:10-cv-11041-NMG

US005879374A

United States Patent [19]

[11] **Patent Number:** **5,879,374**

[45] **Date of Patent:** **Mar. 9, 1999**

Powers et al.

[54] **EXTERNAL DEFIBRILLATOR WITH AUTOMATIC SELF-TESTING PRIOR TO USE**

[75] Inventors: **Daniel J. Powers**, Bainbridge Island; **David Cameron**; **Clinton S. Cole**, both of Seattle; **Thomas D. Lyster**; **Steven T. Mydynski**, both of Bothell; **Carlton B. Morgan**, Bainbridge Island, all of Wash.

[73] Assignee: **Heartstream, Inc.**, Seattle, Wash.

[21] Appl. No.: **240,272**

[22] Filed: **May 10, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 63,631, May 18, 1993, abandoned.

[51] **Int. Cl.**[6] **A61N 1/39**

[52] **U.S. Cl.** **607/5**

[58] **Field of Search** 607/4, 5, 3, 6–8; 324/403, 415, 500, 512, 519, 523, 525, 527; 330/2

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Primary Examiner—William E. Kamm
Attorney, Agent, or Firm—James R. Shay; Cecily Anne Snyder

[57] **ABSTRACT**

A defibrillator with an automatic self-test system that includes a test signal generator and a defibrillator status indicator. The test system preferably performs functional tests and calibration verification tests automatically in response to test signals generated periodically and/or in response to predetermined conditions or events and indicates the test results visually and audibly. The invention also relates to a method for automatically determining and indicating a defibrillator's status without human intervention.

73 Claims, 7 Drawing Sheets

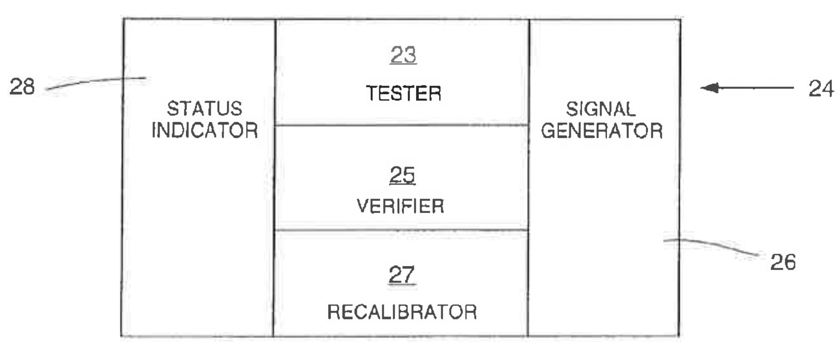

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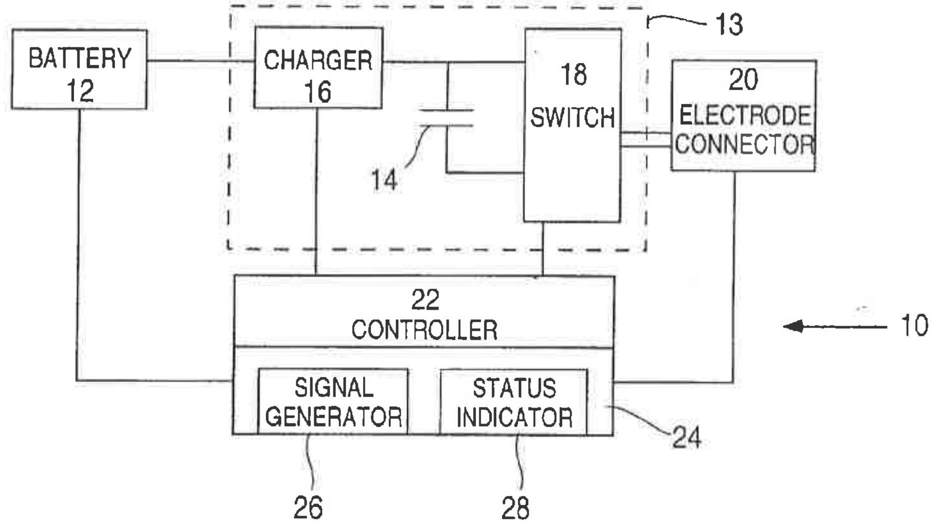
Exhibit-6.00001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12
CHARGER
16
18
SWITCH
20
ELECTRODE
CONNECTOR
14
22
CONTROLLER
10
SIGNAL
GENERATOR
STATUS
INDICATOR
24
26
28

FIG. 1

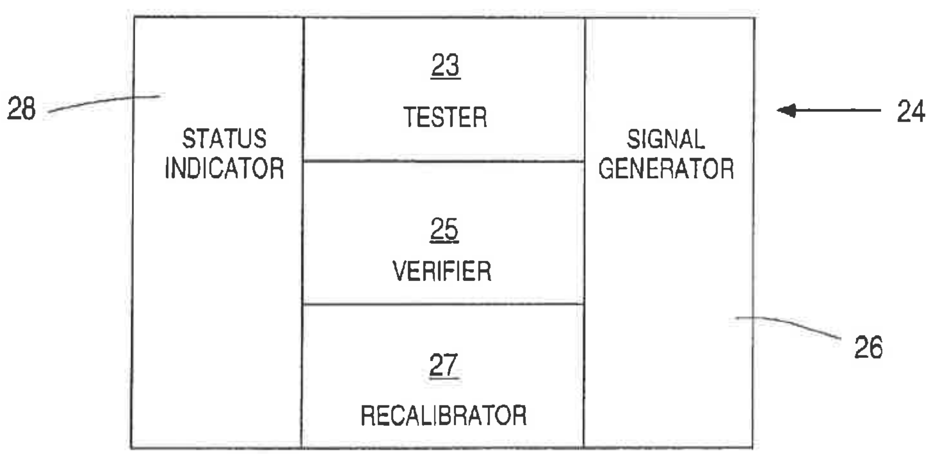
28
STATUS
INDICATOR
23
TESTER
25
VERIFIER
27
RECALIBRATOR
SIGNAL
GENERATOR
24
26

FIG. 2

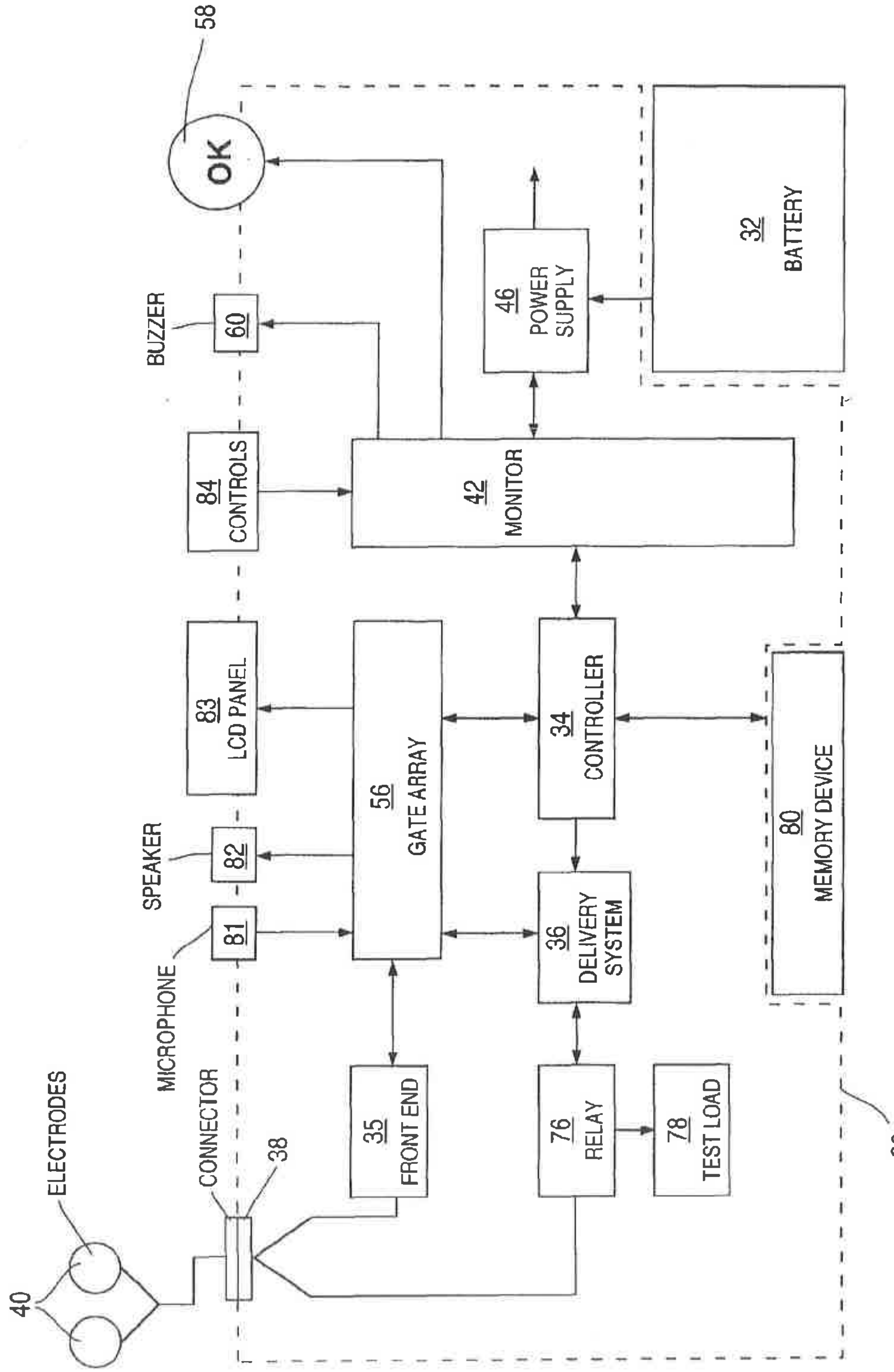

FIG. 3

PHI00073909

Exhibit-6.00003

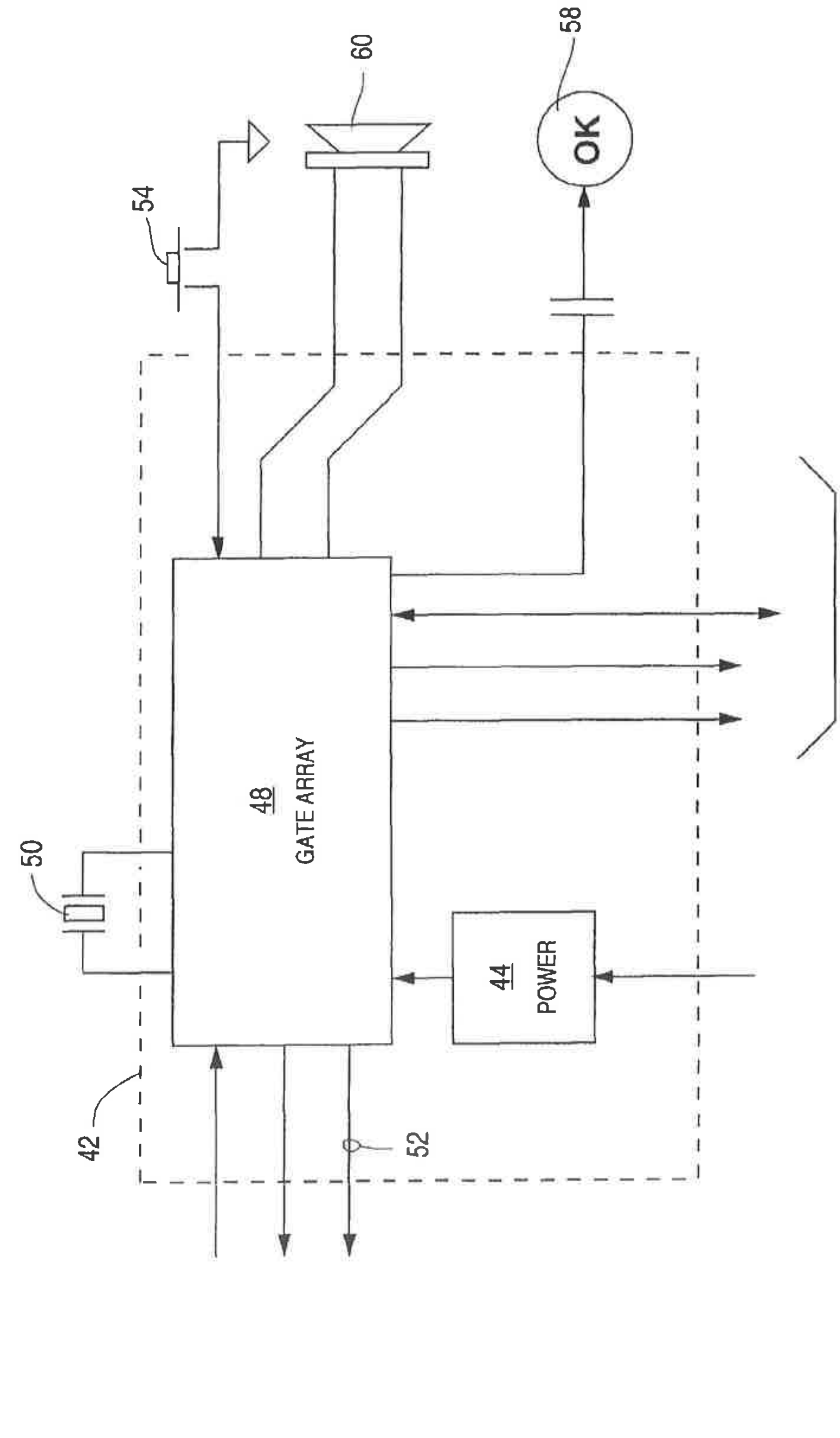

FIG. 4

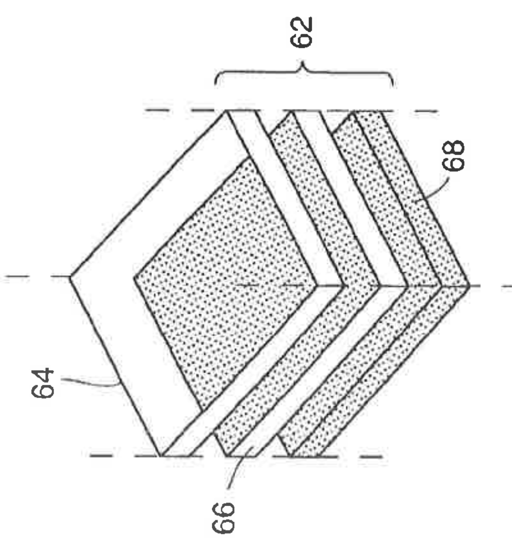

FIG. 5a

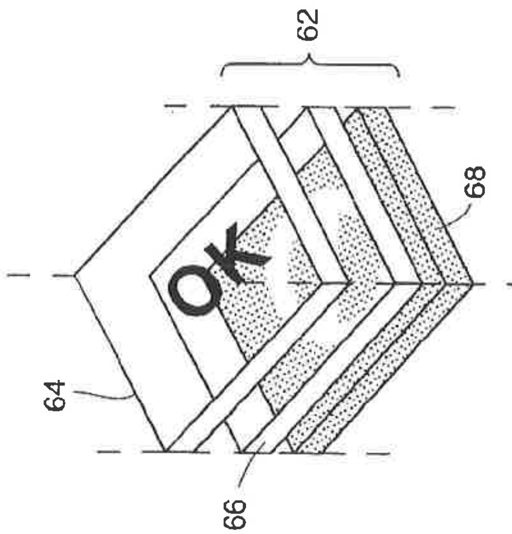

FIG. 5b

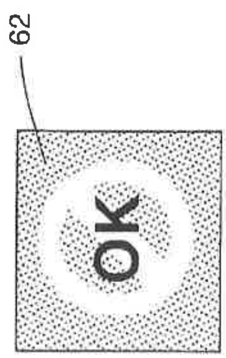

FIG. 5c

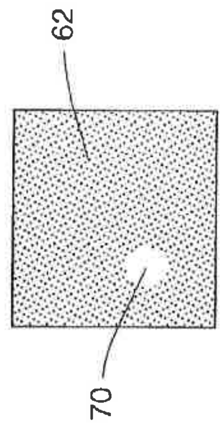

FIG. 5d

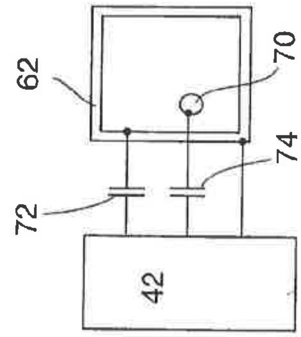

FIG. 5e

TEST DESCRIPTION	BIT	WPST	MPST	DPST	POST	RUN TIME
CPU SELF-TEST	X	X	X	X	X	
SYSTEM GATE ARRAY	X	X	X	X	X	
SYSTEM MONITOR GATE ARRAY	X	X	X	X	X	
PROGRAM ROM CRC	X	X	X	X	X	
SYSTEM RAM CHECKSUM	X	X	X	X	X	
VIDEO RAM CHECKSUM	X	X	X			
DEVICE FLASH ROM CHECKSUM	X	X	X			
SYSTEM WATCH DOG	X	X	X	X	X	X
PCMCIA CARD VERIFY	X					
FRONT END GAIN	X	X	X	X		
ARTIFACT SYSTEM	X	X	X	X		
CMR CHANNEL	X	X	X	X		
DEFIBRILLATOR CONN/RELAY	X	X	X	X		
BATTERY SENSE CELL MEASUREMENT	X	X	X	X	X	X
BATTERY SENSE CELL LOAD MEASUREMENT	X	X	X	X	X	X
BATTERY STACK LOAD CHECK	X	X	X	X	X	X
POWER SUPPLIES CHECK	X	X	X	X	X	X
HV ISOLATION RELAY	X	X	X			
HIGH VOLTAGE DELIVERY SUBSYSTEM	X	X	X			
WAVEFORM DELIVERY						X
CALIBRATION STD. VOLTAGE	X	X	X	X	X	X
CALIBRATION STD. TIME	X	X	X	X	X	X
CALIBRATION STD. RESISTANCE	X	X	X			
STUCK BUTTON TEST	X	X	X	X		
BUTTON TEST	X					
LIGHT ALL LED'S	X				X	
LCD TEST PATTERN	X					
LCD BACKLIGHT VERIFY	X					
SPEAKER OUTPUT TEST	X				X	
PIEZO BEEPER TEST	X				X	

FIG. 6

PHI00073912

Exhibit-6.00006

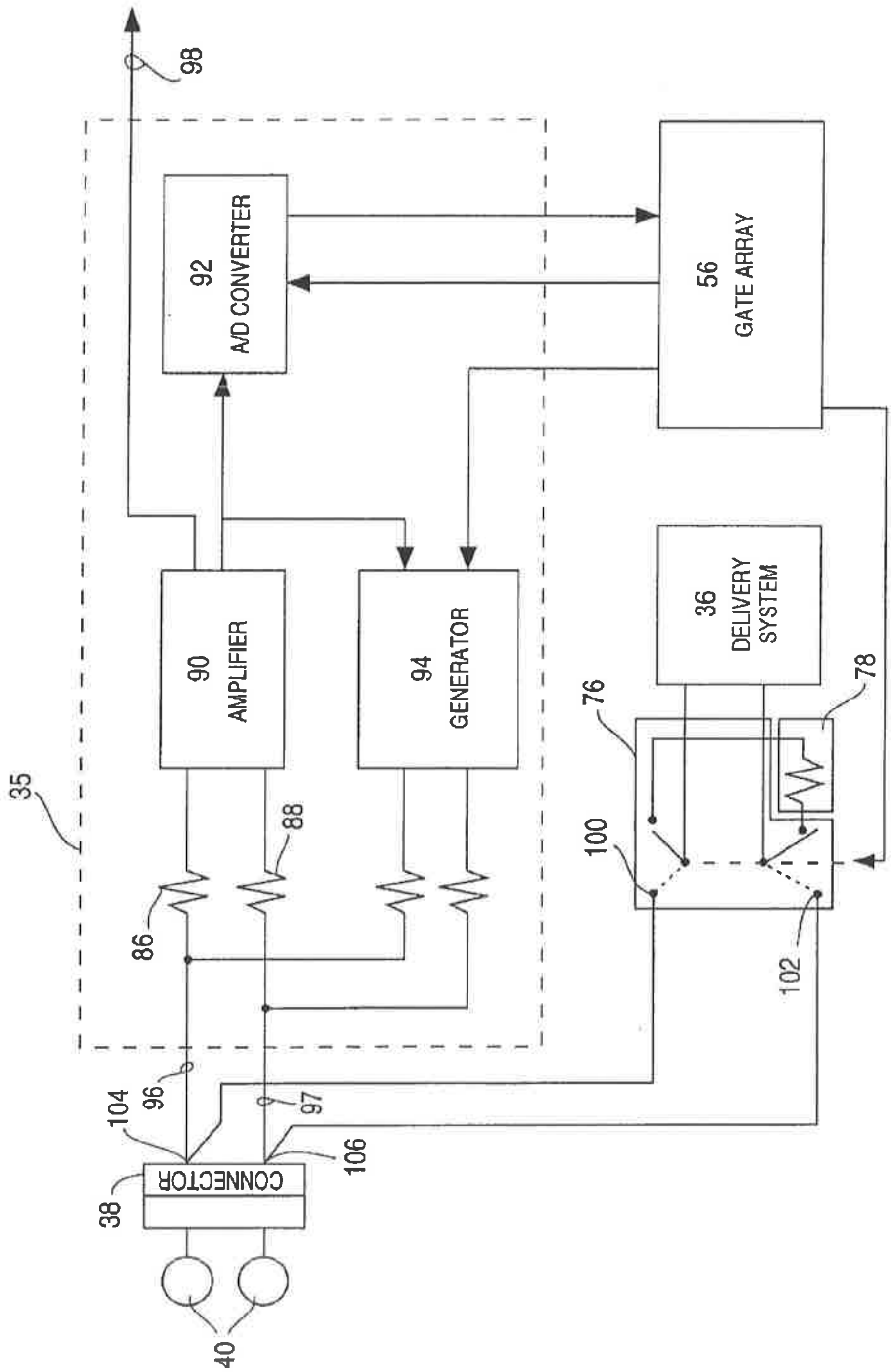
98
92
A/D CONVERTER
56
GATE ARRAY
90
AMPLIFIER
94
GENERATOR
36
DELIVERY
SYSTEM
35
76
78
100
102
86
88
96
97
104
106
CONNECTOR
38
40

FIG. 7

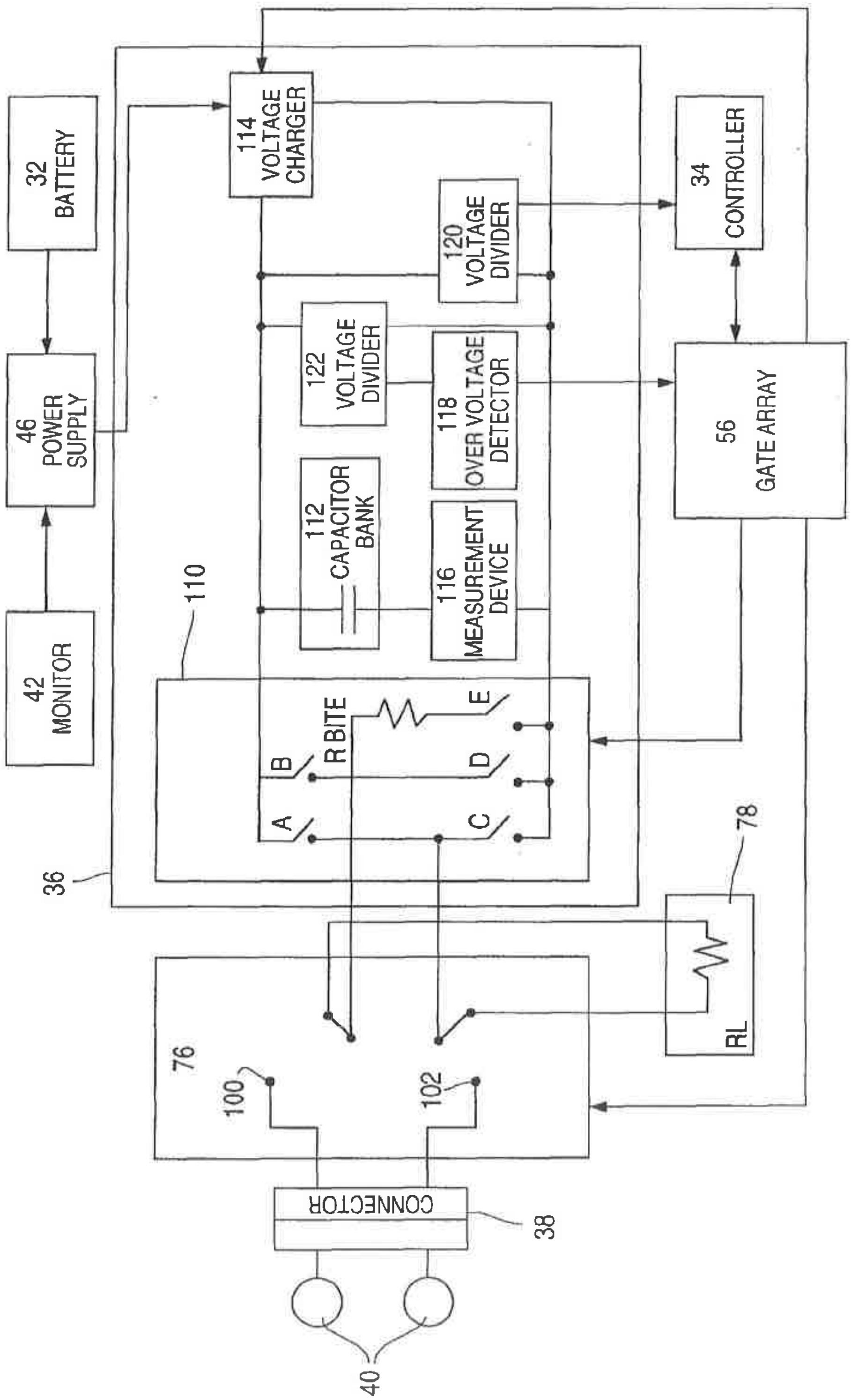
32 BATTERY
46 POWER SUPPLY
42 MONITOR
114 VOLTAGE CHARGER
120 VOLTAGE DIVIDER
122 VOLTAGE DIVIDER
118 OVER VOLTAGE DETECTOR
112 CAPACITOR BANK
116 MEASUREMENT DEVICE
34 CONTROLLER
56 GATE ARRAY
110
36
A
B
C
D
E
R BITE
78
RL
76
100
102
CONNECTOR
38
40

FIG. 8

EXTERNAL DEFIBRILLATOR WITH AUTOMATIC SELF-TESTING PRIOR TO USE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 08/063,631, filed May 18, 1993, now abandoned the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to a defibrillator system that performs periodic self-tests and, in particular, to a method and apparatus for performing periodic functional, calibration and safety tests in an automatic external defibrillator to verify that the defibrillator's components and operation are within preset specifications.

Prior art external defibrillators were used primarily in the hospital. In that environment, the frequency with which a particular defibrillator was used was relatively high, e.g., on the order of several times per week. Periodic verification tests for these prior art defibrillators typically amounted to a battery level test and a functional test in which the defibrillator was hooked to a test load and discharged. These tests were usually performed once per day or once per shift per manufacturer recommendations. Other tests, such as recalibration of internal circuit components by a biomedical technician, were performed less often, on the order of twice per year, also pursuant to manufacturer recommendations. Each of these maintenance tests for prior art defibrillators was initiated and performed by human operators.

SUMMARY OF THE INVENTION

While adequate for relatively frequently-used hospital-based defibrillators, prior art defibrillator test apparatuses and procedures are not optimal for use with portable defibrillators that are used less frequently. For example, defibrillators carried by emergency medical vehicles might need to be used only on a monthly basis. The burden of performing manual battery and performance tests on a daily basis could outweigh the benefits of carrying the infrequently-used defibrillator on the vehicle. The tests should therefore be performed by the defibrillator automatically.

Because the tests are performed automatically, the tests should be both accurate and reliable. The portable defibrillator's mobile environment could add to the frequency of defibrillator component failure, thus increasing the need for periodic tests. In addition, portable defibrillators could be exposed to environmental conditions (such as severe vibration, sudden impacts, heat or moisture) that require an immediate reevaluation of a defibrillator's operational status.

Also, the nature of the tests performed should be different in the portable defibrillator environment because of the relatively infrequent use of the defibrillators. Deterioration of system components over time could move the defibrillator out of its originally specified operating parameters. An infrequently used defibrillator should provide an operator with an indication not only of whether it will operate at all but also verify that the defibrillator meets its established specifications.

Defibrillators are used in emergency situations in which time is of the essence. The operational status of a particular defibrillator as determined by the self-tests should be therefore readily apparent to an operator.

Finally, there is a need for a defibrillator that can automatically recalibrate itself if certain of its system components drift from their initial values. This automatic recalibration minimizes the burden on the defibrillator's operator or maintainer and lengthens the defibrillator's useful life.

This invention is a defibrillator with an automatic self-test system that includes a test signal generator and a defibrillator status indicator. The test system preferably performs functional tests and calibration verification tests automatically in response to test signals generated periodically and/or in response to predetermined conditions or events and indicates the test results visually and audibly. The invention also relates to a method for automatically determining and indicating a defibrillator's status without human intervention.

The invention is described in more detail below with respect to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram showing a defibrillator according to this invention.

FIG. 2 is a schematic diagram showing a testing system of a defibrillator according to this invention.

FIG. 3 is a block diagram showing some of the components of an external defibrillator according to a preferred embodiment of this invention.

FIG. 4 is a block diagram showing the system monitor of the embodiment of FIG. 3.

FIG. 5, parts (*a*)–(*e*) shows various aspects of a visual display according to the embodiment of FIG. 3.

FIG. 6 is a table showing groupings of external defibrillator self-tests according to a preferred embodiment of this invention.

FIG. 7 is a block diagram showing the interaction of an ECG front end and a testing system according to a preferred embodiment of this invention.

FIG. 8 is a block diagram showing the interaction of a high voltage delivery system and a testing system according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

This invention is a method and apparatus for automatically determining the status of a defibrillator, for displaying that status to a user or operator, and, for recalibrating certain defibrillator components. The invention is particularly useful for increasing the reliability of infrequently-used defibrillators by providing an indication of a defibrillator's operational status and by recalibrating the defibrillator, where possible, prior to any attempted use of the defibrillator.

In a preferred embodiment, the defibrillator automatically generates a test signal either (1) periodically in response to the passage of time or (2) in response to a specified event or condition, such as the insertion of a new battery or a manual power-up command from an operator. The test signal initiates a plurality of preset self-tests within the defibrillator. The self-tests may include functional tests that verify the operation of certain defibrillator components and subsystems. The self-tests may also include calibration verification tests that determine whether certain defibrillator components and subsystems are operating at preset

specifications or within preset specification ranges. In addition, the defibrillator may automatically recalibrate certain components or subsystems in response to a calibration verification test.

No matter what test or collection of automatic self-tests the defibrillator performs, the defibrillator indicates its operational status as determined by the self-tests, such as through a visual display. The indication is preferably fail-safe so that a failure of the status indication mechanism itself will result in the indication of an inoperable defibrillator status.

FIG. **1** is a schematic representation of a defibrillator constructed and operated according to this invention. The defibrillator **10** includes a battery **12**, a high voltage delivery system **13** (preferably consisting of a capacitor or capacitor bank **14**, a capacitor charger **16** and a switching mechanism **18**), an electrode connector **20** and a controller **22** that operates the charger and switching mechanism to deliver an electric shock from the capacitor to electrodes connected to the electrode connector or interface **20**. The defibrillator has a testing system **24** including a test signal generator **26** and a defibrillator status indicator **28**. The purpose of testing system **24** is to test the operational status of the defibrillator's components and to provide an indication of that status automatically in response to predetermined events or conditions and/or periodically on a preset schedule.

While the testing system **24** and controller **22** are shown in FIG. 1 as separate elements, they could be combined into a single element that performs all testing and operational control functions. In addition, the testing system **24** may also include components located within other defibrillator subsystems, such as within the high voltage delivery system. In any event, the testing system communicates with the tested defibrillator components and systems via communication channels to control the tests and to gather information about the status of the tested components. The testing system also communicates indicator control signals to the status indicator via communication channels as well.

FIG. **2** is a schematic drawing showing self-testing subsystems making up testing system **24** in the preferred embodiment. It is not necessary that a given defibrillator include each of the subsystems shown in FIG. 2. According to this invention, the defibrillator must include at least one automatic self-test that is initiated in response to a test signal generated either periodically or as a result of a specified event or condition.

Also, it is not necessary for the apparatus performing each test in each subsystem to be in the same physical location. FIG. **2** is a logical grouping and is not intended to be an actual drawing of a defibrillator or defibrillator subsystem.

Each self-test in each group of FIG. **2** responds to a test initiation signal from signal generator **26**, and the result of each self-test in each group affects the status is indicated on status indicator **28**. This collection of self-testing subsystems may be added to or subtracted from without departing from the invention. In addition, while there may be other tests performed by the defibrillator that do not meet these criteria, such tests form no part of this invention.

The first testing subsystem is the functionality tester **23**. The self-tests performed by this subsystem test the operability and functionality of defibrillator components and/or subsystems. Examples include the testing of switches within the switching mechanism of the high voltage delivery system and the testing of registers within the defibrillator's controller.

The second testing subsystem is the calibration verifier **25**. The self-tests performed by this subsystem determine

whether certain defibrillator components and/or subsystems meet preset specifications. Examples include determining the capacitance of the defibrillator's capacitor and checking the response of the controller to capacitor voltage values.

The testing system also may include a recalibrator **27** that adjusts a component or subsystem of the defibrillator in response to a determination that the component or subsystem is no longer, or no longer operates, at a specified value or within a specified range of values. For example, parameters used by the defibrillator's controller to control operation of the high voltage delivery system may be changed to reflect changes in the values of defibrillator components.

The actual self-tests automatically performed by a defibrillator's testing system depend in part on the defibrillator's structure and in part on reliability goals set by the defibrillator's designer. Trade-offs may be made between the completeness of a given self-test (which adds to the reliability of the defibrillator product) and the cost of implementing a complete and accurate self-test. A particular implementation of a defibrillator and its self-testing system is described below. The discussion merely illustrates a preferred embodiment of the invention. Our invention covers other defibrillator designs and other collections of defibrillator self-tests as well.

FIG. **3** is a block diagram showing a preferred configuration for the defibrillator of this invention. Some of the elements are described in more detail further below. Defibrillator elements not specifically described in this application may be configured and operated in the manner described in U.S. patent application Ser. No. 08/227,553, now U.S. Pat. No. 5,607,454 "Electrotherapy Method and Apparatus," filed Apr. 14, 1994, the disclosure of which is incorporated herein by reference.

As shown in FIG. **3**, external defibrillator **30** has a power source such as a removable battery **32**, a controller such as CPU **34**, and a high voltage delivery system **36** including a capacitor or capacitor bank and appropriate switches (not shown) to deliver a pulse of electrical energy to an electrode connector or interface **38** and then to a patient via electrodes **40**. Delivery of the electrical pulse is controlled by CPU **34**. A test and isolation relay **76** and a test load **78** are provided for reasons explained below.

An ECG front end system **35** acquires and preprocesses the patient's ECG signals through electrodes **40** and sends the signals to CPU **34** via a system gate array **56**. System gate array **56** is a custom application specific integrated circuit (ASIC) that integrates many of the defibrillator's functions, such as display control and many of the instrument control functions, thereby minimizing the number of parts and freeing up main CPU time for use in other tasks. The system gate array could be replaced by discrete logic and/or another CPU, of course, as known in the art.

The external defibrillator shown in FIG. **3** also has a memory device **80** (such as a removable PCMCIA card or a magnetic tape), a microphone **81**, a speaker **82**, a LCD panel **83** and a set of illuminated push-button controls **84**. None of these elements is critical to the present invention.

A system monitor mediates the external defibrillator's self-testing functions by watching for scheduled test times and unscheduled power-on events. The system monitor generates test signals periodically at scheduled times and in response to specified events. The system monitor is also responsible for operating a fail-safe defibrillator status indicator or display. The system monitor communicates test signals to the CPU via a communication channel, and the

CPU controls and gathers information from tested defibrillator components via other communication channels, some of which pass through system gate array **56**.

In the embodiment shown in FIG. **3**, system monitor **42** is separate from CPU **34** so that power can be provided to the system monitor without powering any other part of the defibrillator. Thus, system monitor **42** has its own power supply **44** apart from the defibrillator power supply **46**, as shown more specifically in FIG. **4**. This dedicated power supply **44** draws approximately 30 microamps from battery **32** and is active whenever power is available from the battery. The dedicated system monitor power supply may also have its own battery apart from the main battery.

As shown in more detail in FIG. **4**, the other major element of system monitor **42** is a low-power gate array **48**. In this preferred implementation, gate array **48** is a 44-pin custom ASIC. Gate array **48** is preprogrammed to perform the functions of the system monitor. As an alternative, the system monitor could be implemented with a low power CPU and/or with discrete logic components.

Gate array **48** operates a 32.768 kHz crystal oscillator to provide the defibrillator testing system's scheduling function. The gate array divides the oscillator's frequency repeatedly to generate periodic (e.g., daily, weekly, monthly) test initiation signals. The system monitor also sends a 32.768 kHz clock signal out on line **52** to be used by the defibrillator system to perform other functions.

In addition to the periodic tests, certain defibrillator self-tests are performed rapidly in response to activation of the defibrillator's ON button (shown schematically as element **54** in FIG. **4**) by an operator. Activation of the ON button **54** prompts the system monitor to generate a power-on test initiation signal.

The system monitor indicates the status of the defibrillator as a result of the periodic and power-on self-tests. The status indicator should be fail-safe so that the indicator will indicate an inoperable status if the system monitor should fail. The system monitor communicates control information to the status indicator through communication channels.

In a preferred embodiment, the system monitor **42** powers a status indicator consisting of a visual display **58** and a piezo buzzer **60** to indicate the operational status of the defibrillator to a user. As shown in more detail in FIG. **5**, visual display **58** may be a multiple-part LCD **62** powered by the system monitor via AC-coupled drive **72**. The top plate **64** of the LCD is a clear window with an "OK" symbol printed on its back. The middle plate **66** is an LCD shutter that is biased so as to be opaque when driven by the system monitor via drive **72**. The bottom plate **68** has an international "Not" symbol on its top surface. Middle plate **66** also includes a separately addressable portion **70** driven by the system monitor via AC-coupled drive **74**.

In operation, the system monitor **42** drives LCD shutter **66** only when confirmation of successful testing is received within an expected time window. The visual display would then appear as in FIG. **5**, part (*d*). Failure to receive proper test confirmation within the allotted time window will cause the system monitor to cease issuing drive signals to shutter **66**. Shutter **66** will then go transparent to superimpose an international "Not" symbol on the "OK" symbol in the LCD as shown in FIG. **5**, part (*c*). The system monitor will also then begin powering a piezoelectric failure alert buzzer **60**, preferably for 200 msec, every 10 sec, so long as there is power enough to do so.

The primary advantages of the visual display of the preferred embodiment are its low power requirements and the fact that it is powered by an AC signal rather than a DC signal. This latter point ensures the display's fail-safe nature, since the shutter of middle plate **66** cannot be maintained opaque without the active involvement of the system monitor generating the AC signal.

Separately addressable portion **70** serves as a positive indication (in addition to the fail-safe "OK" symbol) that the defibrillator has power and is functioning properly. Portion **70** blinks periodically through the alternating driving and releasing of the signal to portion **70** through drive **74**.

In an alternative embodiment, an LCD shutter covering an "OK" symbol is driven open to display the "OK" symbol to indicate an operational defibrillator status. The shutter is permitted to close to cover the "OK" symbol to indicate that the defibrillator is not operational. Another alternative category of fail-safe indicators include electromechanical devices, such as those used for aircraft instrumentation.

In response to the generation of a test initiation signal, the system monitor commands the defibrillator's power system to turn on. The CPU then issues an appropriate series of commands to perform the required tests. The tests performed in response to the periodic and power-on test initiation signals are described in more detail further below with reference to the table shown in FIG. **6**.

FIG. **6** shows the scheduling of some of the tests that can be performed by the self-test system of this invention. Some of the tests are performed when a battery is inserted, some are performed daily, some are performed weekly, some are performed monthly, some are performed when an operator powers-up the external defibrillator, and some are performed during operation of the defibrillator. FIG. **6** is not an exhaustive list of possible tests, nor is performance of any particular test listed in FIG. **6** essential to the invention. The tests and test groupings shown in FIG. **6** are merely an example illustrating this invention.

The first test grouping is the Battery Insertion Test or BIT. The BIT tests all internal subsystems, allows the user to verify PCMCIA card type, setup parameters, and the proper operation of systems that are only externally observable (e.g., LCD operation and button functionality). The BIT is performed whenever a good battery is inserted into the defibrillator, unless the defibrillator's electrodes are attached to a patient.

The second test grouping shown in FIG. **6** is the Monthly Periodic Self-Test (MPST). The MPST performs the same automated tests as the BIT, but in order to conserve power it does not run the externally observable systems (e.g., LCD, LED's, etc.). The MPST is performed once every 28 days so long as a good battery is maintained in the defibrillator.

The third test grouping shown in FIG. **6** is the Weekly Periodic Self-Test (WPST). The WPST performs essentially the same automated tests as the MPST, except the test shock is not performed in order to conserve power. The WPST is performed once every 7 days so long as a good battery is maintained in the defibrillator.

The fourth test grouping shown in FIG. **6** is the Daily Periodic Self-Test (DPST). The DPST performs fewer tests than the WPST in order to conserve power.

The fifth test grouping shown in FIG. **6** is the Power-On Self-Test (POST). The POST is performed whenever an operator turns the defibrillator from OFF to ON in preparation for use of the defibrillator on a patient. The tests performed in the POST are selected to provide the highest confidence of instrument functionality in the shortest possible time.

The final grouping of tests in FIG. **6** is the Runtime Tests. These tests are performed continually during runtime to

assess the safety and effectiveness of portions of the defibrillator. The tests are explained in more detail below.

The self-tests listed in FIG. 6 are not necessarily listed in the order performed. The performance order depends in part on the interrelationship of the components and functions tested. To the extent there is no such relationship, then the self-test order is arbitrary.

In general, failure of a self-test results in an indication of an inoperable status or error status by the defibrillator's status indicator. For example, in the defibrillator described above, failure of a self-test would result in the display of the "Not OK" symbol by the system monitor and activation of the audible failure signal. The system monitor takes this action if it receives a signal from the CPU or from the system gate array that a test has failed (i.e., that a tested component is not functional or that the component's calibration could not be verified) or if the system monitor does not receive information showing that the currently-scheduled self-test has passed before the expiration of the watchdog's time-out period (e.g., 200 msec.).

In a preferred embodiment of this invention, self-test scheduling and result information may be stored in system memory for later diagnosis of the defibrillator by a technician or operator. For example, in the defibrillator described above, date and time information regarding the self-tests performed are stored in internal memory and/or in the removable memory **80** (e.g., PCMCIA card) so that a history of performed tests can be obtained by a technician or operator. In addition, if a self-test indicates that a component or subsystem is not functional or is out of calibration, or if any recalibration has been performed, detailed information about that test is stored in internal memory and/or in removable memory. Information regarding environmental conditions (temperature, humidity, moisture, impacts) may also be stored for use in later diagnosis.

The CPU self-test is a functional test. During the CPU self-test the CPU tests its internal register integrity and verifies its access to local and external memory locations. If the CPU does not pass these initial tests, it attempts to notify the user of a system failure by writing to a system failure register in the system monitor, resulting in a status display showing "Not OK". If the CPU does not respond to the system monitor within 200 msec of power on, the system monitor assumes the CPU is dead, and the "Not OK" symbol is displayed.

The System Gate Array self-test is also a functional test. In the System Gate Array self-test, the CPU verifies that it can write to and read from the system gate array register set. This test also tests other components of the system gate array, such as whether defibrillator waveform control state machines are functioning correctly. Test failures are handled as for the CPU self-test above.

The System Monitor Gate Array self-test is a functional test as well. The System Monitor Gate Array self-test verifies that the CPU can write to and read from the system monitor.

At the beginning of the Program ROM CRC (Cyclic Redundancy Check) self-test, the CPU resets the system monitor watchdog and executes a CRC on program ROM. This test is a functional test.

In the System RAM Checksum self-test (a functional test), RAM used for data memory is verified using a test pattern that has a high probability of identifying both address and data faults within RAM. Once the pattern has been written to system RAM, the test calculates a checksum based on the system RAM contents.

In the Video RAM Checksum self-test, RAM used for video memory is verified in the same manner as for the system RAM. This self-test is a functional test.

In the Device Flash ROM Checksum self-test, a checksum of the voice data pointer and voice data record is calculated and compared with the checksum value stored in the internal flash ROM. This self-test is a functional test as well.

In the System Watchdog Verify self-test, the CPU verifies the watchdog by writing a known watchdog time-out into the watchdog register and looping until the watchdog time-out register in the system monitor indicates that the watchdog timer has expired. During this test, the watchdog outputs, NMI, and RESET are disabled. The CPU signals a failure if the watchdog timer does not expire within the expected time frame.

The PCMCIA Card Verify self-test is a functional test that checks for the presence and type of the removable memory.

The next four self-tests listed in FIG. 6—Front End Gain, Artifact System, CMR Channel, and Defibrillator Connector/Relay—are all part of the ECG front end tests. These tests verify the functionality and verify the calibration of the ECG input circuitry and the patient/electrode connection circuitry. These tests are not performed during the POST since the tests assume that there is no load attached to the defibrillator output connector.

An explanation of some special features of the external defibrillator of this invention is required as background for the ECG front end tests. FIG. 7 shows the ECG front end **35** in relationship to the system gate array **56**, the high voltage delivery system **36**, a test and isolation relay **76** and the patient connector **38**, as well as communication channels among some of these elements. The test and isolation relay **76** is normally in the state shown in FIG. 7 so that no shock can be delivered from the high voltage delivery system **36** to the patient connector **38** and to the electrodes **40** attached to a patient.

In this state, any signals from electrodes **40** will pass through a pair of protective resistors **86** and **88** to an ECG amplifier **90**. A high resolution A/D convertor **92** digitizes the ECG data and sends it to the system gate array **56** for processing by the CPU to determine whether a shock is required. The system gate array **56** also sends control signals to the A/D convertor **92**.

The ECG front end **35** also has a patient/electrode connection tester consisting of a signal generator **94** connected to the ECG signal input lines through a pair of protection resistors. The signal generator **94** receives input from the ECG analog output and carrier frequency commands from the gate array. The patient/electrode connection tester also produces an artifact test signal which is sent through ECG amplifier **90** to the CPU via line **98**. ECG signal collection and analysis and artifact detection are not part of the present invention.

During automated testing, the system gate array **56** uses the signal generator **94** as a test signal injector to verify the function of the various ECG front end elements, wiring to the patient connector **38**, and the normally-open contacts of the test and isolation relay **76**. To test the ECG processing elements, the system gate array **56** causes the signal generator **94** to inject a small, low-frequency signal mimicking the amplitude and frequency characteristics of an ECG signal, thereby simulating a patient being monitored by the defibrillator. As the frequency of this test signal is varied, the digital data stream from the system gate array is checked by the CPU for values indicative of proper gain and filtering

characteristics of the ECG front end, thus verifying the functionality and calibration of the analog and A/D conversion pathways.

In the Defibrillator Connector/Relay self-test, the function of the test and isolation relay contacts **100** and **102** and patient connector wiring are tested. The system gate array **56** causes the signal generator **94** to emit a 100 microamp, 600 Hz test signal and concurrently switches the test and isolation relay **76** to the normally-open position (shown in phantom in FIG. **7**). The test current signal is carried to a 4-wire connection **104** and **106** directly on the patient connector contacts, through the relay common connection, and into the high voltage delivery subsystem **36**, where both signal lines are held at ground potential. The relay **76** is then switched to its normally closed position. Carrier voltage is measured in both positions is indicative of the resistance of the circuit tested. When the relay is in normally open position, the carrier voltage should be approximately equal to the full scale voltage of signal generator **94**. When the relay is in the normally closed position, carrier voltage should be approximately zero.

Finally, in the Artifact System self-test, the system gate array causes the signal generator **94** to emit signals indicative of artifact generation at the electrodes. Proper receipt of artifact signals of the expected amplitude at the CPU verifies the function and calibration of this channel.

There are three battery-related self-tests that are members of each of the test groupings in the preferred embodiment. The battery tests described below are based on a defibrillator design using the battery capacity indicator described in U.S. patent application Ser. No. 08/182,605, now U.S. Pat. No. 5,483,165 filed Jan. 14, 1994, (specifically, the embodiment of FIG. **2**) the disclosure of which application is incorporated herein by reference. Other battery charge sensor arrangements and other battery charge subsystem self-tests may be used, of course, without departing from the scope of the invention.

The Battery Sense Cell Measurement self-test listed in FIG. **6** refers to a battery capacity test described in Ser. No. 08/182,605 now U.S. Pat. No. 5,483,165 in which a parameter of a single battery cell is monitored to determine the remaining capacity of the entire battery. In the preferred defibrillator configuration, this functional self-test determines whether the remaining battery capacity is sufficient for performing one more use of the defibrillator by determining whether the voltage of the sense battery cell is above a threshold value of approximately 2 volts. If not, then a Low Battery Warning State is entered. If this state is entered during a BIT, DPST, WPST or MPST, the unit returns to Stand-by mode displaying the "Not OK" symbol. If this state is entered during a POST or during runtime, the user is alerted by a symbol appearing on the LCD display **83** and with an audible prompt.

The second listed battery self-test is the Battery Sense Cell Load Check. This calibration verification self-test verifies the sense cell additional load circuitry described in Ser. No. 08/182,605 now U.S. Pat. No. 5,483,165 by turning the additional load circuitry on and off and measuring the voltage load across the load resistor. This test can actually be performed while performing the first battery self-test.

The third listed battery self-test is the Battery Stack Check. This functional test measures the voltage of the entire battery cell stack as a cross-check against the Battery Sense Cell Measurement test. If a portion of the battery stack other than the sense cell has been damaged, the voltage of the entire stack could be different than that which would have been expected based on the sense cell test.

In the Power Supplies Check calibration verification self-test, the system monitor activates the defibrillator's power supply system to supply power to all of the instrument's elements. Scaled representations of the voltages from the supplies are input for verification to the main CPU A/D convertor. For example, the major power supplies are: +18 volt switched battery; +5 volt for system monitor; +5 volts for main logic and analog; −5 volt for analog only; −14 to −22 volt CPU adjustable for LCD bias; +20 volts for IGBT switch drives; +2.5 volt reference for ECG front end; +5 volt reference for main CPU A/D convertor; and 50 ma current source supply for LCD backlight (tested by voltage developed). In addition, the high voltage supply is tested by its ability to charge the capacitor.

The HV Isolation Relay self-test determines the functionality of the test and isolation relay **76**. In the first part of the test, the system gate array **56** moves the test and isolation relay to its normally open position, i.e., with the switches against contacts **100** and **102**. The ECG front end measures the impedance across conductors **96** and **97**. If the measured impedance corresponds to a predetermined impedance value, then the relay passes this part of the test.

The ECG front end then measures the impedance across conductors **96** and **97** with the test and isolation relay **76** in the normally closed position shown in FIG. **7**. The measured impedance should be high (>14 k Ohms). If not, either a load is present at electrodes **40** or the relay failed to move completely to the normally closed position. In either case, the test fails, and the system monitor displays the "Not OK" symbol on the status indicator. In addition, failure to meet both parts of the Isolation Relay test prevents the defibrillator from performing the High Voltage Discharge Test described below.

Under normal conditions, the defibrillator used to implement and practice the preferred embodiment of this invention delivers a biphasic waveform to the patient, as described in more detail in U.S. patent application Ser. No. 08/227,553now U.S. Pat. No. 5,607,454. FIG. **8** provides further information regarding the preferred defibrillator's high voltage delivery system and how its operation is verified and calibrated during self-test.

High voltage delivery system **36** has a capacitor or capacitor bank **112** which can be charged to a preset voltage through a high voltage charger **114** connected to the power supply system **46** and battery **32**. Operation of the high voltage charger is controlled by system gate array **56**. A high voltage switch **110** consisting of five switches A–E and a shunt resistor R_{BITE} controls delivery of the biphasic waveform from capacitor **112** to the patient connector **38** through test and isolation relay **76** under the control of system gate array **56**.

Information regarding charge, current and voltage parameters at the capacitor is provided to system gate array **56** by a current and charge measurement device **116**, an overvoltage detector **118** and a voltage divider **120**. As described in more detail in Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454, current and charge measurement device **116** is preferably a comparator that trips when a preset charge amount has been transferred from capacitor **112**. The time required for this charge transfer is determined by system gate array **56** and is used to determine first and second phase durations via a look-up table in system gate array **56**. All information and control signals pass among the elements via communication channels, some of which are shown schematically in FIG. **8**.

As explained in Ser. No. 08/227,553 now U.S. Pat. No. 5,697,454, resistor R_{BITE} is part of an overcurrent protection

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mechanism to protect circuit components from the effects of high current in the event that the impedance load between electrodes **40** is too low. Unless the initial current as measured by current and charge measurement device **116** is below a preset threshold, R_{BITE} is kept in the waveform delivery circuit to limit the current flowing from capacitor **112** through the switching mechanism **110**.

The high voltage delivery system has an overvoltage protector that protects switching circuit components from the effects of excessive voltage in the event of a higher than expected patient load resistance by preventing any transition from a first biphasic waveform phase to a second biphasic waveform phase. Analog voltage information from the capacitor is fed from a voltage divider **122** to an overvoltage detector **118**. Overvoltage detector **118** is preferably a comparator that trips at a preset voltage. The status of the comparator is communicated to system gate array **56**, which controls operation of the switching mechanism **110**.

Finally, analog information regarding the charge state of capacitor **112** is sent to CPU **34** via voltage divider **120**, where it is converted to digital form. This capacitor voltage information is used by the CPU to control capacitor charging.

The High Voltage Delivery Subsystem self-test actually includes a number of individual self-tests. Capacitor **112** is charged to full voltage (e.g., approx. 1710 volts). As the capacitor voltage rises, the calibration of the overvoltage detector **118** is checked to see that it trips at the proper threshold voltage. If it fails to trip, the system gate array returns a signal to the system monitor to show "Not OK" on the status indicator.

After the capacitor has been fully charged, the system gate array **56** sets the high voltage switch **110** to its normal initial discharge position (switches A and E closed, all other switches open) and commences discharge of the capacitor through the test and isolation relay **76** to the test load resistance R_L. R_L simulates the load of a patient to whom the defibrillators electrodes may be attached. R_L is preferably approximately 10 ohms, however, which is smaller than the minimum allowable patient resistance for the defibrillator. This low resistance assures that the test stresses all of the elements tested in the high current pathways for worst-case patient conditions.

During this part of the High Voltage Delivery self-test, the system gate array verifies overcurrent detection calibration by determining whether the CPU correctly identifies the overcurrent condition detected by current and charge measurement device **116**. The system gate array also checks for proper operation of the charge threshold detector and that the overvoltage detector **118** trips properly when the capacitor voltage drops below the safe voltage threshold, in both cases by determining whether these events occur at their expected times. If either of these parameters is not its expected value, the system monitor displays "Not OK" on the status indicator.

As the capacitor voltage drops during discharge through the test load, the current measured by the current and charge measurement device **116** drops as well. The CPU marks the time the current drops below the overcurrent threshold (t_0). As the current continues to fall, the CPU marks the time (t_1) that the current reaches a value that is 37% of the overcurrent threshold. The difference of these two times is the time constant given by the product of the capacitor value C and the series resistance:

$$t_1-t_0=(R_L+R_{BITE})^{\times} C.$$

Switch D is then closed to short out R_{BITE}. This results in another overcurrent situation, and the CPU once again marks the time (t_2) of capacitor decay to the overcurrent threshold and the time (t_3) to 37% of the threshold. Since R_{BITE} has been removed,

$$t_3-t_2=R_L{}^*C.$$

Since the time measurements can be made very accurately, the relationships between the resistive and capacitive components (and therefore their calibration) can be verified very accurately as well:

$$\frac{t_1-t_0}{t_3-t_2}=\frac{R_L+R_{BITE}}{R_L}$$

$$C=\frac{t_3-t_2}{R_L}$$

If the calculated resistance value differs from the expected value by more than a predetermined amount (e.g., 1%), or if the calculated capacitance value differs from the expected value by more than a predetermined amount (e.g., 5%), the system monitor displays the "Not OK" symbol.

In the preferred embodiment, the gain of the comparators of the current and charge measurement subsystems are determined by the particular values of the components used during assembly of the device. Due to allowable tolerance variation of the components, the times that the currents pass associated threshold values (t_0 and t_2) may vary from ideal values (t_0(ideal) and t_2(ideal)). Actual values of t_0 and t_2 are measured during self-test of the instrument and compared to stored t_0(ideal) and t_2(ideal). If the actual values of t_0 and t_2 measured during the High Voltage Discharge Test differ from the ideal values by less than a preset amount, then the gain on the comparator of the current and charge measurement device **116** is automatically recalibrated by the CPU to a range closer to the ideal value. If the actual values differ from the ideal by the preset amount or more, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

In a similar manner, the expected time for times for the measured charge delivery to cross the charge threshold used to determine first and second phase durations in normal operation is compared to the actual time. If the difference is less than a preset value, the CPU recalibrates the phase durations by recalculating the phase duration values according to a predetermined equation and storing the new values in the look-up table. Alternatively, the CPU could simply replace the original look-up table with another that is correlated with a particular time difference. If the time difference is equal to or greater than the preset value, then the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

Another feature of the external defibrillator of preferred embodiment is an undercurrent detector. If the patient to whom the electrodes are attached has an impedance greater than a specified value, or if one of the electrodes has become dislodged or unattached, in normal operation the defibrillator's discharge will abort. This condition is detected by the current and charge measurement device **116** in conjunction with the CPU.

The High Voltage Delivery self-test verifies calibration of the undercurrent detector by determining whether the low current condition is detected as the capacitor continues its discharge and the discharge current falls. If the CPU fails to detect the undercurrent condition, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

After the capacitor has completely discharged, it is recharged and discharged through the second current path by

opening all switches in high voltage switch **110**, then closing switches B and C. Many of the same parameters described above can be measured to verify the functionality of switches B and C.

The Waveform Delivery self-test is performed only while the defibrillator is operating in normal mode (e.g., connected to a patient). The defibrillator evaluates the measured and calculated waveform parameters after each delivered shock to determine if the waveform was delivered as expected. For example, if the defibrillator is constructed and operated according to U.S. patent application Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454, the defibrillator will analyze waveform parameters such as start voltage, phase **2** end voltage, phase **1** duration and phase **2** duration. If the delivered waveform parameters cannot be reconciled with other information available to the defibrillator, the defibrillator warns the operator of a potential fault condition by, e.g., displaying a warning on the defibrillator's LCD.

The three Calibration Standard self-tests are an automatic way of verifying that defibrillator system standards have not drifted out of calibration. The standards are the values of R_L, R_{BITE}, the system monitor clock, the CPU clock, the CPU A/D convertor reference voltage and the ECG front end A/D convertor reference voltage. For all test groupings except the run time test, the voltage references are checked against each other to determine if either has drifted far enough from its expected value to affect the accuracy of the defibrillator. Specifically, the analog reference voltage for the ECG front end A/D convertor (which has an expected value of 2.5 volts in the preferred embodiment) is measured by the CPU A/D convertor. If the measured digital value differs from 2.5 volts by more than a predetermined tolerance, then at least one of the two reference voltages (i.e., either the ECG front end A/D convertor reference voltage or the CPU A/D convertor reference voltage) has drifted so far so as to affect the reliability of the device.

The time references are cross-checked in a similar way. The CPU counts the clock pulses from the system monitor clock for a predetermined amount of time (as measured by the CPU clock). If the number of counted system monitor clock pulses differs from its expected value by more than a predetermined amount, then at least one of the two clocks has drifted out of the tolerance range.

In addition, as discussed above, the High Voltage Delivery self-test cross-checks the values of R_L and R_{BITE}. Verification of the calibration of all three sets of reference variables is a prerequisite to the overcurrent detection calibration and charge threshold detection calibration described above.

In normal stand-by mode, the contacts beneath all buttons should be open. The Stuck Button self-test determines whether any of the contacts are closed. If so, the test returns a "Not OK" signal.

The remaining tests require user intervention and/or observation and are therefore part of only the BIT or POST test groupings. In the Button test, the user is prompted to depress identified buttons on the instrument to determine whether the buttons are functioning properly. All of the other tests run without user intervention. They each require the user to observe that the defibrillator elements tested are functioning correctly.

In addition to performing the self-tests according to the periodic schedule and in response to the battery insertion and operation of the defibrillator (as shown in FIG. **6**), a group of self-tests can be performed automatically in response to environmental events, such as mechanical shock, e.g. as in a fall (as measured by an accelerometer); vibration (also as measured by an accelerometer); the invasion of moisture into the defibrillator housing (as measured by a humidity sensor); or exposure of the defibrillator to temperature extremes (as measured by a thermocouple, thermistor or other temperature sensor).

Variations of the structure and methods described above are within the scope of this invention. Tests and test structures may be tailored to meet the needs of a particular defibrillator design and its intended use environment.

What is claimed is:

1. An external defibrillator comprising:

a high voltage delivery system comprising an energy source, an electrode interface and a switch connecting the energy source to the electrode interface;

a controller operably connected to the high voltage delivery system; and

a self-test system comprising a defibrillator status indicator, a test signal generator, and means for operating the defibrillator status indicator and the test signal generator prior to any attempted use of the defibrillator.

2. The defibrillator of claim **1** wherein the self-test system further comprises a functionality tester and communication channels between the functionality tester and the test signal generator and between the functionality tester and the status indicator.

3. The defibrillator of claim **2** wherein the self-test system further comprises a communication channel between the functionality tester and the switch.

4. The defibrillator of claim **2** wherein the self-test system further comprising a communication channel between the functionality tester and the controller.

5. The defibrillator of claim **2** wherein the self-test system further comprises a relay having an operational position and a test position, the self-test system further comprising a communication channel between the functionality tester and the relay.

6. The defibrillator of claim **1** wherein the self-test system further comprises a calibration verifier and communication channels between the calibration verifier and the test signal generator and between the calibration verifier and the status indicator.

7. The defibrillator of claim **6** further comprising an overcurrent detector, the self-test system further comprising a communication channel between the calibration verifier and the overcurrent detector.

8. The defibrillator of claim **6** further comprising an undercurrent detector, the self-test system further comprising a communication channel between the calibration verifier and the undercurrent detector.

9. The defibrillator of claim **6** further comprising an overvoltage detector, the self-test system further comprising a communication channel between the calibration verifier and the overvoltage detector.

10. The defibrillator of claim **6** further comprising an ECG front end, the self-test system further comprising a communication channel between the calibration verifier and the ECG front end.

11. The defibrillator of claim **6** wherein the high voltage delivery system comprises a resistor, the self-test system further comprising a communication channel between the calibration verifier and the resistor.

12. The defibrillator of claim **11** wherein the controller comprises means for using the high voltage delivery system resistor as a reference standard for the defibrillator.

13. The defibrillator of claim **11** further comprising a second resistor in communication with the controller, wherein the controller comprises means for using the high voltage delivery system resistor and the second resistor together as reference standards for the defibrillator.

14. The defibrillator of claim 6 wherein the high voltage delivery system comprises a capacitor, the self-test system further comprising a communication channel between the calibration verifier and the capacitor.

15. The defibrillator of claim 6 wherein the controller comprises a clock, the self-test system further comprising a communication channel between the calibration verifier and the clock.

16. The defibrillator of claim 15 wherein the controller comprises means for using the controller clock as a reference standard for the defibrillator.

17. The defibrillator of claim 16 further comprising a second clock in communication with the controller, wherein the controller comprises means for using the controller clock and the second clock together as reference standards for the defibrillator.

18. The defibrillator of claim 6 further comprising a reference voltage source, the self-test system further comprising a communication channel between the calibration verifier and the voltage source.

19. The defibrillator of claim 18 wherein the controller comprises means for using the reference voltage source as a reference standard for the defibrillator.

20. The defibrillator of claim 19 further comprising a second voltage source in communication with the controller, wherein the controller comprises means for using the first and second voltage sources together as reference standards for the defibrillator.

21. The defibrillator of claim 1 further comprising a battery, the self-test system further comprising a battery condition tester and communication channels between the battery condition tester and the battery, between the battery condition tester and the status indicator, and between the battery condition tester and the test signal generator.

22. The defibrillator of claim 1 wherein the test signal generator comprises a system monitor.

23. The defibrillator of claim 22 wherein the system monitor comprises an application specific integrated circuit.

24. The defibrillator of claim 22 further comprising a controller power supply, wherein the system monitor comprises a system monitor power supply separate from the controller power supply.

25. The defibrillator of claim 22 wherein the system monitor further comprises means for generating periodic test signals.

26. The defibrillator of claim 22 wherein the system monitor further comprises means for generating test signals in response to specified events or conditions.

27. The defibrillator of claim 26 further comprising means for receiving a removable battery and for connecting a battery to the high voltage delivery system, in which the event or condition is the insertion of a battery into the defibrillator.

28. The defibrillator of claim 22 in which the event or condition is environmental.

29. The defibrillator of claim 28 in which the environmental event or condition is temperature.

30. The defibrillator of claim 28 in which the environmental event or condition is moisture.

31. The defibrillator of claim 28 in which the environmental event or condition is mechanical shock.

32. The defibrillator of claim 28 which the environmental event or condition is vibration.

33. The defibrillator of claim 22 wherein the system monitor comprises a watchdog timer.

34. The defibrillator of claim 1 wherein the status indicator comprises a sound generator.

35. The defibrillator of claim 1 further comprising memory and a communication channel between the self-test system and the memory.

36. The defibrillator of claim 1 wherein the status indicator comprises a visual display.

37. The defibrillator of claim 36 in which the visual display comprises means for providing fail-safe operation.

38. A defibrillator comprising:

a high voltage delivery system comprising an energy source and a switch connecting the energy source to the exterior of the defibrillator;

a controller operably connected to the high voltage delivery system; and

a self-test system comprising a defibrillator status indicator, a test signal generator, and a recalibrator.

39. The defibrillator of claim 38 further comprising a current sensor, the self-test system further comprising a communication channel between the recalibrator and the current sensor.

40. The defibrillator of claim 38 further comprising a waveform shape controller, the self-test system further comprising a communication channel between the recalibrator and the waveform shape controller.

41. An external defibrillator comprising:

a high voltage delivery system comprising an energy source, an electrode interface and a switch connecting the energy source to the electrode interface;

a controller operably connected to the high voltage delivery system; and

a self-test system comprising a defibrillator status indicator, a periodic test signal generator, and means for operating the defibrillator status indicator and the periodic test signal generator prior to any attempted use of the defibrillator.

42. A method for automatically determining and indicating an operational status of an external defibrillator, the method comprising the following steps:

generating a test signal within the external defibrillator automatically and periodically;

performing a self-test in response to the test signal; and

indicating the operational status of the defibrillator based on a result of the self-test;

the generating, performing and indicating steps being performed prior to any attempted use of the defibrillator.

43. An external defibrillator comprising:

a high-voltage delivery system; and

a self-test system, the self-test system comprising a test signal generator and a fail-safe visual display.

44. A method for automatically determining and indicating an operational status of an external defibrillator, the method comprising the following steps:

generating a test signal within the external defibrillator automatically in response to a predetermined event or condition;

performing a self-test in response to the test signal; and

indicating the operational status of the defibrillator based on a result of the self-test;

the generating, performing and indicating steps being performed prior to any attempted use of the defibrillator.

45. The method of claim 44 wherein the step of generating a test signal within the defibrillator automatically in response to a predetermined event or condition comprises

generating a test signal within the defibrillator automatically in response to insertion of a battery into the defibrillator.

46. The defibrillator of claim 44 in which the step of generating a test signal within the defibrillator automatically in response to a predetermined event or condition comprises generating a test signal within the defibrillator automatically in response to an environmental event or condition.

47. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to temperature.

48. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to moisture.

49. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to mechanical shock.

50. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to vibration.

51. The method of claim 44 wherein the step of performing a self-test comprises determining functionality of a defibrillator component or system.

52. The method of claim 44 wherein the step of performing a self-test comprises verifying calibration of a defibrillator component or system.

53. The method of claim 52 wherein the step of performing a self-test comprises performing a calibration verification self-test, the method further comprising the step of recalibrating a defibrillator component or system in response to the calibration verification self-test.

54. The method of claim 52 wherein the step of performing a self-test comprises discharging a capacitor and measuring electrical and time values associated with the capacitor's discharge.

55. The method of claim 52 wherein the step of performing a self-test comprises using a resistance within the defibrillator as a reference value.

56. The method of claim 52 wherein the step of performing a self-test comprises using two resistances within the defibrillator as reference values through a comparison of two resistance values.

57. The method of claim 52 wherein the step of performing a self-test comprises using a voltage source within the defibrillator as a reference value.

58. The method of claim 52 wherein the step of performing a self-test comprises using two voltage sources within the defibrillator as reference values through a comparison of two voltage source values.

59. The method of claim 52 wherein the step of performing a self-test comprises using a clock within the defibrillator as a reference value.

60. The method of claim 52 wherein the step of performing a self-test comprises using two clocks within the defibrillator as reference values through a comparison of two clocks.

61. The method of claim 44 wherein the indicating step comprises displaying status information on a visual display.

62. The method of claim 61 wherein the displaying step comprises providing an active display signal to the visual display, the visual display having a first state when provided with the active display signal and a second state when not provided with the active display signal, the second state indicating a nonoperational state of the defibrillator.

63. The method of claim 62 wherein the step of providing an active display signal comprises providing an AC signal.

64. The method of claim 44 wherein the indicating step comprises providing audible status information.

65. The method of claim 44 wherein the step of generating a test signal within the defibrillator automatically in response to a predetermined event or condition comprises generating a test signal within the defibrillator automatically in response to the passage of time.

66. The method of claim 44 wherein the step of performing a self-test comprises recalibrating a defibrillator component or system.

67. A method for testing and indicating an operational status of an external defibrillator comprising the following steps:

generating a test signal within the external defibrillator automatically and periodically;

performing a plurality of self-tests in response to the test signal to determine the operational status of a plurality of components of the defibrillator, the tests being performed without human intervention prior to any attempted use of the defibrillator; and

indicating the operational status of the defibrillator in response to at least one of the self-tests.

68. The method of claim 67 wherein the generating step comprises generating a test signal within the defibrillator automatically on a predetermined schedule.

69. The method of claim 67 further comprising the step of generating a test signal within the defibrillator automatically in response to a predetermined event.

70. The method of claim 69 further comprising the step of generating a test signal within the defibrillator automatically in response to an environmental condition or event.

71. The method of claim 67 wherein the step of performing a plurality of self-tests comprises determining functionality of a defibrillator component or system.

72. The method of claim 71 wherein the step of performing a plurality of self-tests comprises verifying calibration of a defibrillator component or system.

73. The method of claim 72 further comprising the step of automatically recalibrating a defibrillator component or system in response to a self-test.

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